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IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS, INC. and ROBERT M. GOLDWYN, M.D.,

Petitioners,

v.

CELIA ANDERSON,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF UTAH

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QUESTIONS PRESENTED

1. Whether Utah's exercise of *in personam* jurisdiction over a non-resident medical association and one of its members violates the Due Process Clause when the defendants' only contacts with Utah are related to their limited voluntary participation outside Utah in a national clinical investigation of a medical device and when other factors render the exercise of jurisdiction unreasonable.

2. Whether the Supreme Court of the State of Utah erred in concluding that a non-resident medical association and one of its members had sufficient minimum contacts with Utah to satisfy the requirements of the Due Process Clause when the contacts between defendants and Utah are comprised solely of defendants' limited voluntary participation in a clinical investigation of a medical device sponsored by a third-party.

LIST OF PARTIES

The parties before the Utah trial court were: petitioners, American Society of Plastic and Reconstructive Surgeons, Inc. and Robert M. Goldwyn, M.D.; respondent Celia Anderson; Broadbent & Woolf, Inc., a Utah professional corporation; Robert M. Woolf, M.D., individually; and Dow Corning Corporation.

The parties before the Supreme Court of the State of Utah were petitioners, American Society of Plastic and Reconstructive Surgeons, Inc. and Robert M. Goldwyn, M.D., and respondent Celia Anderson. Broadbent & Woolf, Robert M. Woolf, M.D., and Dow Corning Corporation did not contest *in personam* jurisdiction in Utah and, as such, were not parties to the appeal to the Utah Supreme Court.

Pursuant to Supreme Court Rule 29.1, petitioners state that petitioner, American Society of Plastic and Reconstructive Surgeons, Inc. has no parent companies or subsidiaries except for one wholly owned subsidiary.

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PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF UTAH

Petitioners, American Society of Plastic and Reconstructive Surgeons, Inc. and Robert M. Goldwyn, M.D., respectfully pray that a writ of certiorari issue to review the judgment and opinion of the Supreme Court of the State of Utah, entered in these proceedings on November 15, 1990.

OPINIONS BELOW

The opinion of the Supreme Court of the State of Utah, to be reported at 807 P.2d 825 (Utah 1990), is reproduced in Appendix A hereto, pp. 1a-9a. The opinion of the Third Judicial District Court for Salt Lake County in the State

of Utah (Russon, J.) has not been reported. It is reproduced in Appendix B hereto, pp. 10a-12a. In addition, Judge Russon rendered an oral opinion in open court which is reproduced in Appendix C hereto, pp. 13a-16a.

JURISDICTION

On September 25, 1987, the District Court of the Third Judicial District for Salt Lake County in the State of Utah granted petitioners' Motion to Quash Service of Process and to Dismiss Plaintiff's Complaint. Appendix B. The trial court also gave an oral opinion in open court setting forth its reasons for granting the motion. Appendix C. On November 15, 1990, the Supreme Court of the State of Utah reversed the decision of the trial court. Appendix A. On February 6, 1991, the Supreme Court of the State of Utah denied petitioners' timely-filed petition for rehearing. Appendix D. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1257 (1988).

CONSTITUTIONAL PROVISION INVOLVED

The Due Process Clause of the Fourteenth Amendment of the United States Constitution provides:

> Section I. . . . nor shall any State deprive any person of life, liberty, or property, without due process of law. . . .

STATEMENT OF FACTS

This action arises out of injuries respondent, Celia Anderson, allegedly suffered as a result of injections of liquid silicone she received as treatment for a severe facial disease. Anderson agreed to participate in a Silicone Injection Study ("Study") sponsored by Dow Corning Corporation ("Dow") and conducted under the auspices of the Food and Drug Administration ("FDA")[1] after her physician, Dr. Robert M. Woolf, diagnosed her as suffering from facial lipodystrophy.[2] The Study involved the use of a sterile injectable silicone fluid (MDX4-4011) utilized for soft tissue reconstruction. The purpose of the Study was to develop a treatment for certain types of severe facial defects for which no other reasonable treatment was available.

American Society of Plastic and Reconstructive Surgeons, Inc. ("ASPRS"), a voluntary membership association of

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[1] Through regulations promulgated under the Food, Drug, and Cosmetic Act, the FDA exercised a substantial degree of control over the implementation of the Study. As sponsor of the Study, Dow was obligated to obtain FDA approval before making the MDX4-4011 available for use in the Study. 21 CFR §§ 312.20, 312.40 (1990). In addition, Dow was responsible for: the selection of qualified investigators; providing the investigators with information necessary to properly conduct the Study; ensuring proper monitoring of the Study and that it was conducted in accordance with the protocol; and ensuring that the FDA and all investigators were promptly informed of significant new adverse effects or risks with respect to MDX4-4011. 21 CFR § 312.50 (1990). Dow received approval from the Drug/Surgical Advisory Committee of the FDA on December 16, 1977.

[2] Facial lipodystrophy is a disease characterized by the progressive and systematic atrophy or wasting away of the fat normally present in a person's face.

approximately 4000 board-certified plastic surgeons practicing in the United States, Canada, and abroad, is an Illinois not-for-profit corporation with its principal place of business in Arlington Heights, Illinois. It has never qualified to do business in Utah, has never had an office or employees in Utah, and has never had an agent for acceptance of service of process in Utah. ASPRS is governed by a Board of Directors, none of whom resides in Utah. ASPRS has never contracted to supply services or goods in Utah, nor has it ever had a telephone listing or bank account in Utah, or owned, used, or possessed any real estate in Utah. ASPRS does not and cannot practice medicine in any State, including Utah, and does not manufacture, sell, or distribute any drug or device (including MDX4-4011). Although meetings of the membership are held on an annual basis, ASPRS has never met in Utah.

ASPRS assisted Dow in developing the protocol[3] for the Study and obtaining FDA approval for the Study. As part of this assistance, ASPRS recommended several plastic surgeons who could serve as the medical monitor for the

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[3] The FDA requires a protocol to be prepared for all clinical studies. The purpose of a protocol is to describe the study. It should include a statement of the objectives and purpose of the study; the names, addresses and qualifications of the investigators involved in the study; the names and addresses of the research facilities used; the name and address of the reviewing Institutional Review Board; the criterion for patient selection and exclusion; a description of the overall design of the study; a description of the methods to be used in determining the doses to be administered; a description of the observations and measurements to be made to fulfill the objectives of the study; and, a description of the clinical procedures, etc. to be taken to monitor the effects of the drug in human subjects and minimize risk. *See* 21 CFR § 312.23(a)(6)(iii) (1990).

Study, as required by the FDA[4]; recommended plastic surgeons who could act as clinical investigators for the Study[5]; recommended geographic regions in which the Study could be conducted; recommended facial hemiatrophy and facial lipodystrophy as the only conditions which would qualify patients to participate in the Study[6]; provided Dow with technical information that Dow used in preparing a consent form (required by the FDA) to be used in connection with the Study; and provided plastic surgeons who would assist Dow in training the clinical investigators in Ann Arbor, Michigan.

Dow had the ultimate responsibility to prepare and submit the protocol to the FDA for approval. Specifically, Dow made the final decision regarding the selection of the medical monitor and clinical investigators. Moreover, Dow chose the geographic regions in which the Study would be conducted, and had ultimate responsibility for the form and content of the consent form. Finally, Dow provided all the MDX4-4011 used in the Study.

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[4] FDA regulations require the sponsor of any clinical investigation, in this case Dow, to "select a monitor qualified by training and experience to monitor the progress of the investigation." 21 CFR § 312.55(d) (1990).

[5] A clinical investigator is responsible for ensuring that the investigation is conducted in accordance with the investigational plan and applicable regulations. 21 CFR § 312.60 (1990). In addition, an investigator is obligated to obtain the informed consent of each person to whom the drug is administered. 21 U.S.C. § 355(i) (1988); 21 C.F.R. § 310.102 (1977).

[6] Facial hemiatrophy is a condition characterized by a congenital or acquired wasting of the skin tissues and bone on one side of the face.

Once Dow received FDA approval, ASPRS' involvement in the Study substantially diminished.[7] Clinical investigators with patients whom they believed qualified for participation in the Study (and who volunteered to participate in the Study), were wholly responsible for seeking approval for their patients to participate in the Study by sending an application to the medical monitor selected by Dow, Dr. Robert M. Goldwyn.

Dr. Goldwyn, a board-certified plastic and reconstructive surgeon, resides in Brookline, Massachusetts, and is licensed to practice medicine only in Massachusetts. Dr. Goldwyn has never been licensed to practice medicine in Utah, nor has he ever advertised in, maintained an office in, or otherwise transacted any business, including the practice of medicine, in Utah. Dr. Goldwyn is not employed as a physician by ASPRS or Dow, nor did he receive any payment for his assistance in the Study except for nominal reimbursement of his administrative costs and expenses. As medical monitor, Dr. Goldwyn was responsible only for screening the medical information of potential participants in the Study (which clinical investigators forwarded to him) to determine whether the applicant satisfied the FDA guidelines for participation in the Study.

One of the twelve geographic regions Dow selected for the Study was Salt Lake City, Utah. Anderson was a patient of Dr. Woolf, the clinical investigator in Salt Lake City, who diagnosed Anderson as having facial lipodystrophy. With Anderson's consent, Dr. Woolf sought approval

[7] While ASPRS members in their individual capacities acted as clinical investigators for the Study, ASPRS' only activity with respect to the Study after it commenced was to see that investigators transmitted to Dow the required reports and follow-up information regarding their patients.

for her participation in the Study by sending medical information regarding her condition to Dr. Goldwyn in Massachusetts. After he reviewed the information submitted, Dr. Goldwyn approved Anderson's participation in the Study. Anderson was subsequently treated by Dr. Woolf with MDX4-4011. As a result of the severe reaction she had to the silicone, Anderson has undergone surgical procedures to remove the silicone.

In 1983, Anderson brought this lawsuit against Dr. Woolf and Dow in Utah State court. ASPRS and Dr. Goldwyn were not named as defendants in the original complaint. During discovery, Anderson learned for the first time of ASPRS' and Dr. Goldwyn's role in providing medical and technical assistance to Dow. Indeed, Anderson has testified that she had not heard of ASPRS or Dr. Goldwyn until after this lawsuit was filed. Anderson subsequently amended her complaint to add ASPRS and Dr. Goldwyn as defendants and served both under Utah's long-arm statute, Utah Code Ann. § 78-27-24 (1987). ASPRS and Dr. Goldwyn moved to quash service of process and dismiss the complaint for lack of personal jurisdiction. The Third Judicial District Court for Salt Lake County of the State of Utah granted this motion. Appendices B & C. Anderson appealed this dismissal to the Utah Supreme Court, which reversed. Appendix A.

In reversing the trial court, the Utah Supreme Court stated that it applied a two-part test to determine whether Utah could properly exercise personal jurisdiction over ASPRS and Dr. Goldwyn. First, the court found that exercising jurisdiction over ASPRS and Dr. Goldwyn was proper under the Utah long-arm statute, Appendix pp. 6a-7a, based upon its conclusion that Anderson had made a *prima facie* showing that ASPRS and Dr. Goldwyn caused injuries to Anderson in Utah, thereby committing a tort

in Utah within the meaning of the Utah long-arm statute. The court then concluded that an assertion of personal jurisdiction over ASPRS and Dr. Goldwyn would not violate the Due Process Clause of the Fourteenth Amendment, Appendix p. 8a, stating:

> Facts supporting this conclusion include the following: ASPRS—(1) its committee selected Salt Lake City as a program site, (2) its committee selected Woolf as a program physician, (3) it assisted in preparing the consent form which it knew would be used in Utah, (4) it (with Dow) selected Goldwyn as monitor of treatment in the program, including anticipated treatment in Utah, (5) it investigated the potential for malpractice claims, including those that might arise in Utah, and (6) it trained Woolf, knowing he would use that training in Utah; Goldwyn—(1) helped draft the consent form, (2) supervised the proper administration of the treatment program in Utah, (3) authorized Anderson's silicone injections, and (4) assumed responsibility to monitor Anderson's treatment and to follow up if there were problems.

Appendix p. 8a.

REASONS FOR GRANTING CERTIORARI

ASPRS and Dr. Goldwyn voluntarily assisted a medical device-manufacturer in the preparation and implementation of a well-directed, controlled, important clinical study intended to advance medical science and develop a new method of treatment for severe and previously untreatable disorders that resulted in the disfigurement of those affected. Neither ASPRS nor Dr. Goldwyn was ever physically present in Utah in connection with this voluntary

assistance. The Utah Supreme Court's decision in this case requires ASPRS and Dr. Goldwyn to submit to a trial in a forum in which they are not present and with which they have no contacts merely because of their assistance to Dow. If permitted to stand, this decision will have a chilling effect on the extent to which medical associations and their members are willing to participate in important clinical investigations.

In reaching its decision that Utah's assertion of personal jurisdiction over ASPRS and Dr. Goldwyn comported with the requirements of due process, the Utah Supreme Court rejected or ignored the teachings of this Court regarding the limits the Due Process Clause places on the various States' exercises of *in personam* jurisdiction over non-resident defendants. For this reason, this Court should issue a writ of certiorari to the Utah Supreme Court. In addition, a writ of certiorari will permit this Court to clarify the confusion currently plaguing the jurisdictional due process inquiry. Finally, a writ of certiorari to the Utah Supreme Court is necessary to reverse the chilling effect which the Utah Supreme Court's decision will have on volunteerism in worthy projects such as Dow's Silicone Injection Study.

I.

THE UTAH COURT FAILED TO CONDUCT A PROPER ANALYSIS UNDER THIS COURT'S TWO-PART DUE PROCESS JURISDICTIONAL INQUIRY

Since this Court's decision in *Pennoyer v. Neff*, 95 U.S. 714 (1878), the Due Process Clause of the Fourteenth Amendment has limited the extent to which a State is permitted to enter binding judgments against non-resident defendants not served within the State's borders. The

scope of the due process restrictions on a State's exercise of *in personam* jurisdiction has undergone continued refinement since the landmark decision in *International Shoe Co. v. State of Washington*, 326 U.S. 310 (1945), in which this Court held that a State may assert jurisdiction over a defendant not found within the State only if the defendant "ha[s] certain minimum contacts with [the State] such that maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.' " 326 U.S. at 316.

As currently interpreted, the jurisdictional due process inquiry contains two separate analyses. First, courts must consider whether the defendant has "purposefully established minimum contacts within the forum State." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 476 (1985). Second, courts must consider the non-resident defendant's purposeful contacts with the forum State in light of other factors to determine whether the exercise of jurisdiction is reasonable, *i.e.*, would comport with "traditional notions of fair play and substantial justice." *Asahi Metal Indus. v. Superior Court of California*, 480 U.S. 102, 113 (1987); *Burger King*, 471 U.S. at 476; *see also Asahi Metal*, 480 U.S. at 116 (Brennan, J., concurring in part and in the judgment).

The Utah Supreme Court failed to conduct the proper due process analyses as set forth in this Court's decisions in *World-Wide Volkswagen v. Woodson*, 444 U.S. 286 (1980), *Burger King*, and *Asahi Metal*. This failure may be the result of the confusion which exists among federal and state courts regarding how the reasonableness factors apply to the jurisdictional due process inquiry. A properly conducted analysis under both prongs of the due process inquiry demonstrates that Utah's assertion of jurisdiction in this case is improper.

II.

THE CONFUSION THAT HAS RESULTED FROM THIS COURT'S DECISIONS IN *WORLD-WIDE VOLKSWAGEN, BURGER KING* AND *ASAHI METAL* UNDERMINES THE GOALS OF CONSISTENCY AND PREDICTABILITY IN JURISDICTIONAL DETERMINATIONS

In the context of personal jurisdiction, the protections afforded by the Due Process Clause give "a degree of predictability to the legal system that allows potential defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit." *World-Wide Volkswagen*, 444 U.S. at 297. Lower courts' interpretations and applications of the competing views set forth in *Asahi Metal* as to the relationship between the two prongs of the due process inquiry have undermined this goal of predictability.[8] Lower courts, both federal and state, have issued numerous conflicting opinions in attempting to apply the analyses set forth in *World-Wide Volkswagen*, *Burger King*, and *Asahi Metal*.

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[8] Quoting Winston Churchill, one federal court has described the jurisdictional inquiry as " 'a riddle wrapped in a mystery inside an enigma.' " *Donatelli v. National Hockey League*, 893 F.2d 459, 462 (1st Cir. 1990). In more direct terms, another federal court has raised the need for a clarification of the standards governing jurisdictional determinations.

> More sharply defined standards might well reduce miscalculations on the part of lawyers who, not surprisingly, normally seek a home court advantage if they think they see some chance of getting it—and it is not inconceivable that clearer standards might lead to more expeditious and efficient resolution of those jurisdictional questions. . . .

Lak, Inc. v. Deer Creek Enterprises, 885 F.2d 1293, 1304 n. 7 (6th Cir. 1989), *cert. denied*, 110 S. Ct. 1525 (1990).

In *Burger King*, this Court stated, "[o]nce it has been decided that a defendant purposefully established minimum contacts within the forum State, these contacts may be considered in light of other factors to determine whether the assertion of personal jurisdiction would comport with 'fair play and substantial justice.' " 471 U.S. at 477. Various courts have interpreted this language to establish purposeful availment as a threshold jurisdictional requirement. For example, the Court of Appeals for the First Circuit has held: "A reviewing court must first examine the defendant's contacts with the forum. If the same do not exist in sufficient abundance, that is, if the constitutionally necessary first-tier minimum is lacking the inquiry ends." *Donatelli*, 893 F.2d at 465.[9] Consistent with this

[9] *See also Chung v. NANA Development Corp.*, 783 F.2d 1124, 1129 (4th Cir.), *cert. denied*, 479 U.S. 948 (1986) ("[b]ecause personal jurisdiction here fails the threshold test of 'minimum contacts,' we need not separately consider the convenience of any particular forum to the respective parties"); *Lak, Inc. v. Deer Creek Enterprises*, 885 F.2d at 1303; *McGlinchy v. Shell Chemical Co.*, 845 F.2d 802, 817-18 n. 10 (9th Cir. 1988); *Ex Parte Pope Chevrolet, Inc.*, 555 So. 2d 109, 112 & n.1 (Ala. 1989) (interpreting *Asahi Metal* to establish purposeful availment as a threshold inquiry); *Grange Ins. Ass'n v. State*, 110 Wash. 2d 752, 765, 757 P.2d 933, 940 (Wash. 1988) (en banc), *cert. denied*, 490 U.S. 1004 (1989) (if purposeful availment not established, court will not consider reasonableness factors); *Wiles v. Morita Iron Works Co., Ltd.*, 125 Ill. 2d 144, 161-62, 530 N.E.2d 1382, 1390 (Ill. 1988); *Goodyear Tire v. Ruby*, 312 Md. 413, 423, 540 A.2d 482, 487 (Md. 1988); *Batton v. Tennessee Farmers Mut. Ins. Co.*, 153 Ariz. 268, 271-72, 736 P.2d 2, 5-6 (Ariz. 1987); *Felix v. Bomoro Kommanditgesellschaft*, 196 Cal. App. 3d 106, 117, 241 Cal. Rptr. 670, 676 (1987); *Superior Supply Co. v. Associated Pipe & Supply Co.*, 515 So. 2d 790, 796 & n. 14 (La. 1987); *Witbeck v. Bill Cody's Ranch Inn*, 428 Mich. 659, 669, 411 N.W.2d 439, 444 (Mich. 1987); *State ex rel. Wichita Falls Gen. Hosp. v. Adolf*, 728 S.W.2d 604, 609 (Mo. App.), *cert. denied*, 484 U.S. 927 (1987). *But see Camelback Ski Corp. v. Behning*, 312 Md. 330, 341, 539 A.2d 1107, 1112 (Md.), *cert. denied*, 488 U.S. 849 (1988) ("although it is convenient to speak of the two analyses as separate steps, the 'threshold' step is not considered in a vacuum, nor must it invariably be the first step").

approach, other courts have considered the reasonableness factors only if the purposeful availment prong has been satisfied.[10]

Following the lead of the O'Connor plurality in *Asahi Metal*, some courts have considered the reasonableness factors even after finding the absence of purposeful availment.[11] Still other courts have adopted the view set forth by Justice Stevens in his concurring opinion in *Asahi Metal* that purposeful availment need not be considered in cases where the jurisdictional determination can be made solely on the basis of reasonableness considerations.[12]

Finally, several courts have apparently ignored the teachings of *Burger King* and *Asahi Metal* by upholding assertions of jurisdiction solely on the basis of purposeful avail-

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[10] *See, e.g., Mesalic v. Fiberfloat Corp.*, 897 F.2d 696, 701 (3d Cir. 1990); *Pittsburgh Terminal Corp. v. Mid Allegheny Corp.*, 831 F.2d 522, 529 (4th Cir. 1987); *Interfirst Bank Clifton v. Fernandez*, 844 F.2d 279, 282 (4th Cir. 1988); *American Greetings Corp. v. Cohn*, 839 F.2d 1164, 1169 (6th Cir. 1988); *Heritage House Restaurants, Inc. v. Continental Funding Group, Inc.*, 906 F.2d 276, 284 (7th Cir. 1990); *Sher v. Johnson*, 911 F.2d 1357, 1364 (9th Cir. 1990); *Equifax Services, Inc v. Hitz*, 905 F.2d 1355, 1359 (10th Cir. 1990); *Williams Elec. Co., Inc. v. Honeywell, Inc.*, 847 F.2d 741, 743 (11th Cir. 1988); *Lebel v. Everglades Marina, Inc.*, 115 N.J. 317, 328, 558 A.2d 1252, 1257 (N.J. 1989).

[11] *See U.S.S. Yachts, Inc. v. Ocean Yachts, Inc.*, 894 F.2d 9, 12-13 (1st Cir. 1990); *Federal Ins. Co. v. Lake Shore, Inc.*, 886 F.2d 654, 661 (4th Cir. 1989); *Dalton v. R & W Marine, Inc.*, 897 F.2d 1359, 1363 (5th Cir. 1990); *Falkirk Mining Co. v. Japan Steel Works, Ltd.*, 906 F.2d 369, 374 (8th Cir. 1990); *Madara v. Hall*, 916 F.2d 1510, 1519 (11th Cir. 1990).

[12] *See FDIC v. British-American Ins. Co., Ltd.*, 828 F.2d 1439, 1442 (9th Cir. 1987); *Fields v. Sedgwick Associated Risks, Ltd.*, 796 F.2d 299, 302 (9th Cir. 1986).

ment; the reasonableness factors were not considered.[13] The Utah Supreme Court appears to have followed this latter approach.[14] In doing so—that is, by failing to conduct a meaningful inquiry into the reasonableness of exercising jurisdiction over ASPRS and Dr. Goldwyn—the Utah Supreme Court avoided having to address and resolve the ambiguities which have plagued other courts in their interpretation of the two-part due process inquiry.

III.

THE ASSERTION OF PERSONAL JURISDICTION BY UTAH OVER ASPRS AND DR. GOLDWYN VIOLATES DUE PROCESS

This Court made it clear in *World-Wide Volkswagen* that, in addition to satisfying the minimum contacts/purposeful availment inquiry set forth in *International Shoe* and its progeny, a State's exercise of jurisdiction over a

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[13] *See North Penn Gas v. Corning Natural Gas*, 897 F.2d 687, 691 (3d Cir.), *cert. denied*, 111 S. Ct. 133 (1990); *English & Smith v. Metzger*, 901 F.2d 36, 39-40 (4th Cir. 1990); *Daniel J. Hartwig Assocs., Inc. v. Kanner*, 913 F.2d 1213, 1216-20 (7th Cir. 1990); *FMC Corp. v. Varonos*, 892 F.2d 1308, 1313-14 (7th Cir. 1990); *Complete Concepts, Ltd. v. General Handbag Corp.*, 880 F.2d 382, 389 (11th Cir. 1989); *Northern Aircraft, Inc. v. Reed*, 572 A.2d 1382, 1386-87 (Vt. 1990) (although recognizing the two-part test, court based assertion of personal jurisdiction solely on purposeful availment).

A survey of the confusion generally existing in the lower federal and state courts would not be complete without noting that certain courts have utilized the two-part due process inquiry set forth by this Court in *Asahi Metal* in "general jurisdiction" cases to which the two-prong inquiry does not apply. *See Dalton v. R & W Marine, Inc.*, 897 F.2d 1359, 1361-63 (5th Cir. 1990); *Bearry v. Beech Aircraft Corp.*, 818 F.2d 370, 377 (5th Cir. 1987); *Schlobohm v. Schapiro*, 784 S.W.2d 355, 358-59 (Tex. 1990).

[14] Both ASPRS and Dr. Goldwyn timely raised this aspect of the due process inquiry in their brief to the Utah Supreme Court.

non-resident defendant must be reasonable. The Utah Supreme Court's conclusion that due process permits the exercise of jurisdiction over ASPRS and Dr. Goldwyn is in error. First, the conclusion that ASPRS and Dr. Goldwyn purposefully established sufficient minimum contacts with Utah is in conflict with the decisions of this Court. Further, a meaningful consideration of the reasonableness factors demonstrates that the exercise of jurisdiction in this case is unreasonable.

A. The Utah Court's Determination That ASPRS And Dr. Goldwyn Purposely Availed Themselves Of The Privilege Of Conducting Activities In Utah Is In Conflict With The Decisions Of This Court

In *International Shoe Co. v. State of Washington*, 326 U.S. 310 (1945), this Court established "minimum contacts" as the appropriate standard to ensure that the exercise of personal jurisdiction does not offend "traditional notions of fair play and substantial justice." Subsequent decisions of this Court made it clear that the "minimum contacts" test could only be satisfied by conduct that was purposefully directed at the forum State *by the defendant.*

> The unilateral activities of those who claim some relationship with a non-resident defendant cannot satisfy the requirement of contact with the forum State. The application of that rule will vary with the quality and nature of the defendant's activity, but it is essential in each case that there be some act by which the defendant *purposefully avails* itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws.

Hanson v. Denckla, 357 U.S. 235, 253 (1958) (citing *International Shoe*) (emphasis added); *see also Kulko v. Superior Court of California*, 436 U.S. 84, 94 (1978) (quoting

Hanson). While recognizing that the expansion of interstate commerce has necessitated some relaxation of the restraint due process places on a State's exercise of jurisdiction over non-resident defendants, this Court has consistently held that the restraint has not been abandoned. *Burger King*, 471 U.S. at 474 ("constitutional touchstone remains whether the defendant purposefully established 'minimum contacts' in the forum State"). *See generally* Perschbacher, *Minimum Contacts Reapplied: Mr. Justice Brennan Has It His Way in* Burger King Corp. v. Rudzewicz, 1986 Ariz. St. L.J. 585.

"This 'purposeful availment' requirement ensures that a defendant will not be haled into a jurisdiction solely as a result of 'random', 'fortuitous', or 'attenuated' contacts . . . or of the 'unilateral activity of another party or third person.' " *Burger King*, 471 U.S. at 475. For this reason, this Court has rejected the proposition that mere foreseeability that an event will occur in another State is sufficient to satisfy due process.

> [T]he foreseeability that is critical to due process analysis is not the mere likelihood that a product will find its way into the forum State. Rather, it is that defendant's conduct and connection with the forum State are such that he should reasonably anticipate being haled into court there.

World-Wide Volkswagen, 444 U.S. at 297. By holding that Utah may exercise jurisdiction over ASPRS and Dr. Goldwyn in this case, the Utah Supreme Court is in direct conflict with this precedent.

In reversing the trial court's order of dismissal, the Utah Supreme Court concluded on the basis of conclusory allegations that ASPRS and Dr. Goldwyn had engaged in "purposeful acts" directed towards Utah sufficient to satisfy due process. ASPRS and Dr. Goldwyn dispute the

propriety of the Utah Supreme Court's factual determinations. Indeed, a careful review of the record in this case demonstrates that none of the Utah Court's factual determinations is supported by competent evidence.

ASPRS did not select Salt Lake City as a program site. Rather, ASPRS only recommended to Dow that Salt Lake City might be suitable as a program site. Dow ultimately selected twelve regional sites from a list of thirty-one proposed by ASPRS which included Salt Lake City. Similarly, ASPRS did not select Dr. Goldwyn as the medical monitor for the Study or Dr. Woolf as a clinical investigator. Rather, ASPRS recommended several physicians whom would be a suitable medical monitor; Dow then selected Dr. Goldwyn. Similarly, Dow selected Dr. Woolf as a clinical investigator from a list of suitable physicians provided by ASPRS.

While ASPRS provided medical expertise to assist Dow in its preparation of the consent form which would be used with all volunteers in the program, ASPRS did not know at that time that the form would be used in Utah. In any event, Dow had ultimate authority regarding the form and content of the consent form which required, and received, FDA approval. Finally, Dow was responsible for training the clinical investigators it selected (including Dr. Woolf). This training program was conducted in Michigan, not Utah, with the assistance of ASPRS members who acted as faculty for part of the program.

Dr. Goldwyn's role as medical monitor was limited to a review of medical information submitted by applicants. If the clinical investigator provided additional information during the course of the treatment, Dr. Goldwyn would review such medical information. It is important to note, however, that clinical investigators were not required to

submit additional information to Dr. Goldwyn. Moreover, he had no responsibility for the actual treatment of patients who volunteered for the Study. Dr. Goldwyn did not supervise Dr. Woolf's participation in the Study generally, nor did he supervise Dr. Woolf's silicone injections of Anderson. Finally, Dr. Goldwyn never assumed any responsibility to monitor Anderson's treatment or any subsequent work necessitated by Anderson's reaction to the silicone injections. Anderson testified that it was only through discovery in this case that she became aware of Dr. Goldwyn's existence. Thus, there is no support for the Utah Supreme Court's conclusion that a physician/patient relationship existed between Dr. Goldwyn and Anderson.

The findings of fact by the Utah Supreme Court are wholly unsupported by competent evidence. By relying on these unsupported findings, the Utah Supreme Court completely eviscerated ASPRS' and Dr. Goldwyn's constitutional right to not be haled into a forum with which neither had established meaningful contacts. Conjecture, speculation and wishful thinking are not substitutes for properly supported *findings* of minimum contacts necessary to assert personal jurisdiction.

Even assuming the Utah Supreme Court properly "found" these jurisdictional facts to exist, such facts do not establish purposeful availment of the benefits of Utah by either ASPRS or Dr. Goldwyn. As to the ASPRS, none of the facts relied upon by the Utah Supreme Court is in any way related to Utah. ASPRS' assistance of Dow by recommending Salt Lake City as a possible program site, Dr. Woolf as a possible program physician, and Dr. Goldwyn as a possible medical monitor, all occurred either in Illinois (where ASPRS is headquartered) or Michigan (where Dow is headquartered). ASPRS' assistance of Dow in the prep-

aration of the consent form was similarly removed from Utah. Finally, the training program in which ASPRS members assisted Dow was conducted in Michigan. As to Dr. Goldwyn, his participation was limited to the pre-screening of applicants to the Study to ensure they met the qualifications for participation set forth in the protocol. The fact that Anderson applied for permission to participate in the Study from Utah and was subsequently approved for admission by Dr. Goldwyn in Massachusetts does not show purposeful availment by Dr. Goldwyn of the rights and privileges of the Utah forum. *Cf. Batton v. Tennessee Farmers Mut. Ins. Co.*, 153 Ariz. 268, 736 P.2d 2 (Ariz. 1987) (defendant's correspondence with plaintiff's attorney does not constitute purposeful availment).

Ultimately, the only arguable contact between ASPRS, Dr. Goldwyn, and Utah that relates to this action was the eventual use by Dr. Woolf of a consent form in Utah. In effect, the Utah Supreme Court has held that ASPRS and Dr. Goldwyn's assistance in preparing this consent form which was subsequently used by a third-party in Utah is a sufficient contact with Utah to establish that ASPRS and Dr. Goldwyn have purposefully availed themselves of the privilege of conducting activities in Utah.

The Utah Supreme Court appears to be applying the "stream of commerce" theory of jurisdiction which courts developed in recognition of the ever-increasing nationwide nature of commercial activity. Using the stream of commerce theory, some courts have held that a defendant who merely places a product into the stream of interstate commerce is subject to jurisdiction in any State into which the product subsequently flows. *See Asahi Metal*, 480 U.S. at 110-11 (discussing conflicting views of the stream of commerce theory).

While this Court has addressed the stream of commerce theory on several occasions, it has yet to definitively decide whether merely placing a product into the stream of interstate commerce is sufficient to justify an assertion of jurisdiction in any State where the product is found. In *World-Wide Volkswagen*, this Court rejected plaintiff's argument that mere foreseeability that a product might find its way into a State can independently constitute purposeful availment such as to satisfy the requirements of due process. 444 U.S. at 295-96. Specifically, this Court held that it would be unreasonable to exercise personal jurisdiction where the defendant had not made any efforts directly or indirectly to market its products in the forum State.

This Court's most recent pronouncement on the stream of commerce theory came in *Asahi Metal*. Justice O'Connor, writing for a plurality of the Court, expressly rejected the stream of commerce theory.

> The "substantial connection" between the defendant and the forum State necessary for a finding of minimum contacts must come about by *an action of the defendant purposefully directed toward the forum State*. The placement of a product into the stream of commerce without more, is not an act of the defendant purposefully directed toward the forum State. Additional conduct of the defendant may indicate an intent or purpose to serve the market in the forum State, for example, designing the product for the market in the forum State, advertising in the forum State, establishing channels for providing regular advice to customers in the forum State, or marketing the product through a distributor who has agreed to serve as the sales agent in the forum State. But a defendant's awareness that the stream of commerce may or will sweep the product into the forum State

> does not convert the mere act of placing the product into the stream into an act purposefully directed toward the forum state.

480 U.S. at 112 (plurality opinion) (citations omitted). In his concurring opinion in which three other justices joined, Justice Brennan disagreed with the plurality's rejection of the stream of commerce theory. 480 U.S. at 116. Thus, there was no clear holding by a majority of this Court on the viability of the stream of commerce theory as a sufficient basis for a State's exercise of jurisdiction over a non-resident defendant.

Since *World-Wide Volkswagen* and *Asahi Metal*, lower courts have continued to struggle with the proper role of the stream of commerce theory in the jurisdictional inquiry. Several courts, while recognizing the confusion regarding the applicability of the stream of commerce theory, have rejected the theory or seriously questioned its merit. *See Federal Ins. Co. v. Lake Shore, Inc.*, 886 F.2d 654, 659 (4th Cir. 1989) (plaintiff may not rely on unadorned stream of commerce theory); *Batton v. Tennessee Farmers Mut. Ins. Co.*, 153 Ariz. 268, 271, 736 P.2d 2, 7 (Ariz. 1987) (noting differing views on viability of stream of commerce theory); *Felix v. Bomoro Kommanditgesellschaft*, 196 Cal. App. 3d 106, 117, 240 Cal. Rptr. 670, 675 (1987) (rejecting stream of commerce theory); *cf. Chung v. NANA Dev. Corp.*, 783 F.2d 1124, 1129 (4th Cir.), *cert. denied*, 479 U.S. 948 (1986) (mere foreseeability that product may reach distant forum not sufficient).

This is an even less appropriate case for application of the stream of commerce test than were *World-Wide Volkswagen* and *Asahi Metal*. In those cases, the defendant was engaged in commercial activity—it obtained revenue and anticipated receiving a profit as a result of placing the

product into the stream of commerce. In this case, there is no commercial motive behind the assistance which ASPRS and Dr. Goldwyn provided Dow in the preparation and conduct of the Study. *Cf. State ex. rel. Wichita Falls Gen. Hosp. v. Adolf*, 728 S.W.2d 604, 609 (Mo. App.), *cert. denied*, 484 U.S. 927 (1987) (noting that providing organs suitable for transplant was not commercial activity of the type commonly found to support jurisdiction). There is no evidence that ASPRS or Dr. Goldwyn ever anticipated achieving any commercial or economic benefit as a result of its assistance with Dow in drafting the consent form.

Thus, this case is unlike all prior cases in which courts, including this Court, have found that a defendant's conduct with respect to the forum State constitutes purposeful availment in the sense of the defendant transacting business in the forum State. As this Court has recognized on numerous occasions, the rationale justifying the substantial expansion of the due process test is the modern reality of conducting business in the United States and the world. *See, e.g., McGee v. International Life Ins. Co.*, 355 U.S. 220, 223 (1957) (expansion of scope of jurisdiction is the result of transformation of national economy). Neither ASPRS nor Dr. Goldwyn were conducting business through their involvement in the Study. Rather, each was participating on a voluntary basis in a Study which promised "societal", as opposed to "personal" benefits.

B. A Proper Consideration of the Reasonableness Factors Establishes that Utah's Assertion of Personal Jurisdiction Over ASPRS and Dr. Goldwyn Violates Due Process

In *World-Wide Volkswagen*, this Court set forth several factors independent of a defendant's purposeful conduct

that are relevant to the consideration of the reasonableness of a State's assertion of personal jurisdiction.

> Implicit in this emphasis on reasonableness is the understanding that the burden on the defendant, while always a primary concern, will in an appropriate case be considered in light of other relevant factors, including the forum State's interest in adjudicating the dispute, the plaintiff's interest in obtaining convenient and effective relief, . . . the interstate judicial system's interest in obtaining the most efficient resolution of controversies; and the shared interest of the several States in furthering fundamental substantive social policies.

World-Wide Volkswagen, 444 U.S. at 292 (citations omitted); *see also Burger King*, 471 U.S. at 477. Indeed, this Court has held that these reasonableness factors can defeat jurisdiction, notwithstanding the fact that the defendant may have purposefully availed itself of the privilege of conducting activities within the forum State. *See Asahi Metal*, 480 U.S. at 113-15 (eight Justices agree that assertion of jurisdiction over defendant would be unreasonable even assuming purposeful availment).

The Utah Supreme Court failed to meaningfully consider the reasonableness of exercising personal jurisdiction over ASPRS and Dr. Goldwyn.[15] In so doing, it violated ASPRS' and Dr. Goldwyn's due process rights by subjecting them to an exercise of Utah jurisdiction which is not reasonable.

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[15] The Utah Supreme Court noted that "Utah's interest in protecting Anderson from injury is compelling," and further alluded in summary fashion to a "[b]alancing of all the competing interests." Appendix p. 8a. The Utah Supreme Court's opinion, however, does not disclose the nature of the balancing allegedly undertaken.

ASPRS, a not-for-profit association of medical professionals, voluntarily agreed to assist Dow in developing a Silicone Injection Study designed to develop a treatment for two severe, essentially untreatable facial disorders. ASPRS had no profit motive with regard to its assistance in the Study. Moreover, the limited nature of ASPRS' assistance of Dow did not involve the delivery of goods or services in Utah. To the contrary, ASPRS' involvement was limited to an advisory role in which it provided medical and technical expertise and recommendations *to assist Dow*, which prepared the protocol, selected a suitable medical monitor, selected suitable clinical investigators, selected suitable geographic locations for the Study, and prepared a consent form. In agreeing to perform this limited function, ASPRS hoped to assist in the development of a treatment for those persons afflicted with the most critical cases of progressive facial hemiatrophy and lipodystrophy. Similarly, Dr. Goldwyn voluntarily agreed to act as medical monitor for the Study. In so doing, Dr. Goldwyn was not motivated by pecuniary gain; indeed, he was not paid for his services. Rather, Dr. Goldwyn was motivated by a recognition of the societal benefits which could result from the Study.

Requiring ASPRS and Dr. Goldwyn to defend this action in Utah would infringe upon the societal interest which all States share in furthering the advancement of medicine and the development of new treatment techniques. The Utah trial court recognized this when it held, separate from its determination that neither ASPRS nor Dr. Goldwyn had purposely availed themselves of the benefits of the Utah forum, that an assertion of jurisdiction would be unreasonable for social policy reasons.

> The study and practice of medicine is such in our society that there is great interchange that goes on between doctors and organizations of doctors, and it

> is all to the betterment of society that these kinds of things occur. But if by participating as they might in non-profit organizations of non-profit enterprises, if they are going to start subjecting one another to [the] jurisdictions of every single state, we will see a chilling effect take place that will be damaging to society at large.

Appendix p. 15a. The trial court's recognition of the societal need for this type of medical research mirrors the recognition of the United States Senate in its discussion of the provisions of the "Medical Device Amendments of 1976" to the Federal Food, Drug and Cosmetic Act.[16]

> As medicine progresses, as research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of American people. The [Health Subcommittee] wants to encourage their research and development. The [Health Subcommittee] also wants to be sure that the FDA has the proper authority to regulate that process so that Americans are not put at risk from the use of unsafe and ineffective medical devices.

S. Rep. No. 94-33, 94th Cong., 2d Sess. 2, *reprinted in* 1976 U.S. Code Cong. & Admin. News 1070, 1071. The Senate further noted, "S. 2368 recognizes the benefits that medical research and experimentation to develop devices offers to mankind." *Id.* at 6, 1976 U.S. Code Cong. & Admin. News at 1075.

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[16] The Medical Device Amendments of 1976 gave the Food and Drug Administration enhanced authority to regulate the testing and distribution of medical devices in the market place. *See* S. Rep. No. 94-33, 94th Cong., 2d Sess. 1, *reprinted in* 1976 U.S. Code Cong. & Admin. News 1070, 1070.

The advancement of medical treatment techniques must necessarily occur through the voluntary participation of professional medical societies, their member physicians, and the manufacturers of medical drugs and devices in the ongoing exchange of medical ideas and treatment techniques. The personal and institutional costs of being subject to jurisdiction in every State in which the fruits of this voluntary participation are tested will have a substantial chilling effect on the extent to which limited participants such as ASPRS and Dr. Goldwyn will be willing to voluntarily contribute to medical studies such as that at issue in this case. *Cf. Grange Ins. Ass'n v. State*, 110 Wash. 2d 752, 763, 757 P.2d 933, 939 (Wash. 1988), *cert. denied*, 490 U.S. 1004 (1989) (court recognized "public policy of ensuring that medical services are fully available to all people, a policy that might be inhibited if doctors were worried about having to defend malpractice suits in distant states"). From society's perspective, this is clearly not a desirable result. Therefore, the interest that all States share in furthering the advancement of medicine renders Utah's assertion of jurisdiction over ASPRS and Dr. Goldwyn unreasonable.

A consideration of the remaining reasonableness factors similarly counsels against an assertion of jurisdiction by Utah. Neither ASPRS nor Dr. Goldwyn disputes the fact that Utah has an interest in adjudicating Anderson's claim. In this case, however, another important state interest weighs against an assertion of Utah jurisdiction. As recognized in *State ex rel. Wichita Falls Gen. Hospital v. Adolf*, 728 S.W.2d 604, 609-610 (Mo. Ct. App.), *cert. denied*, 484 U.S. 927 (1987), all States have a vital interest in protecting and improving the life and health of their citizens. This interest is furthered by each State exercising its jurisdictional authority in a manner that does not discourage the free exchange and development of medical

data and information. The Missouri court in *Adolf* rejected plaintiff's claim that a Texas hospital should be subject to jurisdiction in Missouri based on its efforts in making known to a Missouri patient the availability of a heart suitable for transplantation. The court stated:

> Hospitals making organs available [for transplant] do so for moral and humanitarian reasons. We know of no legal requirement [sic] they do so and we know of no reason why they could not simply refuse to make transplantable organs available or limit the forums to which they will make them available. . . . If the threat of having to defend a potential malpractice action, meritorious or otherwise, in a far distant jurisdiction serves to cause even one hospital to refuse to provide an organ necessary to keep a Missouri resident alive the results far outweigh the inconvenience of requiring Missouri residents to sue in the hospital's home forum.

728 S.W.2d at 610.

This societal concern applies with equal force here. An assertion of jurisdiction by Utah in this case will set a precedent permitting each and every State in which this Study, or any other clinical study of a new drug or device, was conducted to exercise jurisdiction over limited participants such as ASPRS and Dr. Goldwyn. This may result in medical professionals deciding to limit their participation in clinical studies conducted for the benefit of *all* persons inflicted with a particular medical condition. Utah, like all other states, has an interest in avoiding this result.[17]

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[17] Anderson has argued that Utah is the most convenient forum for her in which to conduct this litigation. As has been noted by both courts and commentators, however, "plaintiff's convenience alone cannot justify the heavy burden on defendants which the assertion of jurisdiction would impose." *Federal Ins. Co. v. Lake Shore, Inc.*, 886 F.2d 654, 661 (4th Cir. 1989); *see also Moore's Federal Practice*, ¶ 4.41-1[4.-1] (2d ed. 1988).

Thus, had the Utah Supreme Court properly considered the reasonableness of asserting jurisdiction over ASPRS and Dr. Goldwyn in this case, it would have affirmed the trial court's determination that to do so would violate the Due Process Clause of the Fourteenth Amendment.

CONCLUSION

For these reasons, this petition for writ of certiorari should be granted to review and reverse the decision of the Supreme Court of Utah.

Respectfully submitted,

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APPENDICES

APPENDIX A

This opinion is subject to revision before publication in the Pacific Reporter.

IN THE SUPREME COURT OF
THE STATE OF UTAH

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Celia Anderson,
Plaintiff and Appellant,

v.

American Society of Plastic and Reconstructive Surgeons, Dr. Robert Goldwyn, Broadbent & Woolf, Inc., a Utah corporation, Robert M. Woolf, individually, and Dow Corning Corporation,
Defendants and Appellees.

No. 870421

FILED
November 15, 1990

Geoffrey J. Butler,
Clerk

Third District, Salt Lake County
The Honorable Leonard Russon

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Ray R. Christensen, Salt Lake City, for Dow Corning Corporation
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DURHAM, Justice:

Plaintiff Celia Anderson ("Anderson") appeals the dismissal of her complaint against defendants American Society of Plastic and Reconstructive Surgeons, Inc. ("ASPRS"), and Dr. Robert Goldwyn ("Goldwyn") (collectively "defendants") for lack of personal jurisdiction. The other defendants have not contested jurisdiction. This appeal follows trial court certification of its interlocutory order under rule 54(b) of our rules of civil procedure. We vacate the trial court's order of dismissal as to both ASPRS and Goldwyn and remand for trial on the merits, with an order to postpone any ruling on personal jurisdiction until after plaintiff has presented her case.

Anderson's claims arise out of experimental therapy she received for a disfiguring condition of her face. The therapy consisted of injections of an experimental liquid silicone product into her face. The liquid silicone was produced by Dow Corning Corp. ("Dow") and injected by Dr. Robert Woolf ("Woolf") (both defendants, but not parties to this appeal). Anderson reacted severely to the silicone, became grossly disfigured, and suffered a great deal of pain. She filed suit against Dow, Woolf, and Woolf's professional corporation for damages, alleging various causes of action.

During discovery, Anderson found out that ASPRS was involved with Dow in setting up and running the experimental silicone injection program. She also learned that Goldwyn was the medical monitor in charge of ensuring that each patient admitted to the program fell within the FDA guidelines, was an appropriate subject for the experimental therapy, and received appropriate follow-up care in the event of complications. She found that he also supervised much of the medical record keeping for the program and performed various other functions.

Anderson amended her complaint to include ASPRS and Goldwyn, claiming that she should not have received the experimental therapy because she did not fit the program's patient profile, that ASPRS—with Dow—violated federal drug law, that she did not give informed consent for the therapy because of defendants' and Dow's preparation of a defective informed consent form, and that Goldwyn was negligent in performing his monitoring duties.

Defendants moved to dismiss Anderson's complaint against them for lack of personal jurisdiction pursuant to rule 12(b)(2) of our rules of civil procedure. They argued that their conduct did not fall within the activities listed in Utah's long-arm statute and that they had insufficient contacts with this forum for it to assert jurisdiction compatible with due process requirements.

The trial court ruled on defendants' motion based on the pleadings and documentary evidence, including depositions and affidavits. It concluded that to assert jurisdiction over defendants would offend due process. It did not make any findings of fact, but in light of conflicts in the documentary evidence before it, we conclude that the court necessarily weighed the facts in order to reach its conclusions.

Anderson's allegation that the district court can assert specific personal jurisdiction over ASPRS and Goldwyn under our long-arm statute, Utah Code Ann. § 78-27-24 (1987), requires a two-part inquiry. *See, e.g., Bradford v. Nagle*, 763 P.2d 791, 793 (Utah 1988). First, do her claims arise from one of the activities listed in the statute? And second, are defendant's contacts with this forum sufficient to satisfy the due process clause of the fourteenth amendment if the trial court exercises jurisdiction? An additional preliminary question is, what burden must a plaintiff bear

to show that the trial court has personal jurisdiction over a defendant? We will address the preliminary question first.

In *Roskelley & Co. v. Lerco, Inc.*, 610 P.2d 1307 (Utah 1980), we held that in a pretrial determination of jurisdiction, a plaintiff cannot rely on allegations made in the complaint if the defendant has specifically controverted alleged jurisdictional facts by affidavit. *Id.* at 1310. However, we did not answer the question of how to resolve factual disputes—such as conflicts between one witness's deposition and another's affidavit—nor did we decide how to proceed when jurisdiction turns on the same facts as the merits of the case. Both of these problems occur in Anderson's case.

We have not had occasion to address these issues before, but the federal courts have done so. Because our rule 12 is patterned after the corresponding federal rule and because the federal courts routinely apply state long-arm statutes to determine the limits of their own jurisdiction, the federal courts' reasoning is helpful. The following is our synthesis of tenth circuit reasoning on these issues as set forth by five representative cases. *See Ten Mile Indus. Park v. Western Plains Serv. Corp.*, 810 F.2d 1518, 1524 (10th Cir. 1987); *Behagen v. Amateur Basketball Ass'n*, 744 F.2d 731, 733 (10th Cir. 1984), *cert. denied*, 471 U.S. 1010 (1985); *Milligan v. Anderson*, 522 F.2d 1202, 1207 (10th Cir. 1975); *Schramm v. Oakes*, 352 F.2d 143, 149 (10th Cir. 1965); *Nova Mud Corp. v. Fletcher*, 648 F. Supp. 1123, 1124-25 (D. Utah 1986).

The approach taken by the federal courts is motivated by concern for flexibility, judicial economy, and preservation of substantial rights. In the federal trial court's discretion, under rule 12 it may determine jurisdiction on affidavits alone, permit discovery, or hold an evidentiary

hearing. If it proceeds on documentary evidence alone (i.e., the first two methods), the plaintiff is only required to make a prima facie showing of personal jurisdiction. The plaintiff's factual allegations are accepted as true unless specifically controverted by the defendant's affidavits or by depositions, but any disputes in the documentary evidence are resolved in the plaintiff's favor. The trial court must not weigh the evidence unless a hearing is held.

Unless an evidentiary hearing is held, the plaintiff must prove jurisdiction at trial by a preponderance of the evidence after making a prima facie showing before trial. When jurisdiction turns on the same facts as the merits of the case, an evidentiary hearing is inappropriate because it infringes on the right to a jury trial and is an inefficient use of judicial resources (hearing the same evidence twice); in such cases—if the plaintiff has made a prima facie showing—jurisdiction is determined by trial on the merits. Pretrial jurisdictional decisions based on documentary evidence are reviewed de novo by the federal appellate courts.

We approve these guidelines as suitable for our trial courts. Applying them to Anderson's case, we hold that she need only have made a prima facie showing that the trial court had personal jurisdiction over defendants in order to proceed to trial on the merits. Because the facts on which personal jurisdiction over defendants is asserted overlap the facts that will determine whether defendants are liable to Anderson, it was proper for the trial court to rule on personal jurisdiction based only on documentary evidence.

The next issue is whether defendants' actions with respect to Anderson fall within the activities enumerated in our long-arm statute. The trial court did not rule on

this issue; it based its ruling on due process considerations only. Defendants argue that they did not "caus[e] any injury within this state" as required by the statute in tort and breach of warranty cases. Utah Code Ann. § 78-27-24(3) (1987). Although we often assume the application of the statute—and go straight to the due process issue—because our legislature has directed us to construe it "so as to assert jurisdiction over nonresident defendants to the fullest extent permitted by the due process clause of the Fourteenth Amendment to the United States Constitution," Utah Code Ann. § 78-27-22 (1987); *see Parry v. Ernst Home Center Corp.*, 779 P.2d 659, 661 (Utah 1989), we do not do so here. Whether defendants caused injury to Anderson is the central question on the merits of her claims. She is entitled to have a jury answer that question if she produces sufficient evidence. *See* Utah Code Ann. §§ 78-21-1, -2 (1987).

Anderson has made a prima facie showing that defendants caused her injuries. She has alleged that she should not have been accepted into the program, and deposition testimony shows that she did not fit the program's patient profile. Other documentary evidence shows that it was Goldwyn's responsibility to make sure that all patients admitted to the program fit the profile. This evidence supports a prima facie case of negligence against Goldwyn and an inference that ASPRS may have been negligent in its supervision of Goldwyn or in preparing guidelines for him. There is documentary evidence that ASPRS participated in the program with Dow as a cosponsor and that both may have violated duties imposed by federal drug law. There is further evidence that ASPRS participated with Dow and Goldwyn in preparing the consent form used by physicians participating in the program. Anderson has alleged that she would not have been injured because

she would not have accepted the therapy if the consent form had disclosed the true nature of the risks. The sum of this and other evidence is that Anderson has made a prima facie showing that defendants caused injuries to her in this state.

The last issue is whether defendants have sufficient minimum contacts with this forum to make exercising jurisdiction over them comport with the demands of due process imposed by the fourteenth amendment (neither party briefed state constitutional due process issues). The trial court based its decision on due process, and defendants make their main argument based on due process. Defendants argue, and the trial court ruled, that they lack sufficient contacts with Utah and this litigation to be subject to personal jurisdiction here.

We last reviewed due process requirements for personal jurisdiction in *Parry v. Ernst Home Center.*[1] Our analysis is the same here. Defendants' contacts with Utah must be "such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.' " *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (quoting *Milliken v. Meyer*, 311 U.S. 457, 463 (1940)). Defendants must have "reasonably anticipate[d] being haled into court" here, *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980), and they must have "purposefully avail[ed]" themselves of the privilege of conducting activities here. *Hanson v. Denckla*, 357 U.S. 235, 253 (1958). The trial court must also balance "the convenience of the parties" and weigh this forum's interest

[1] Although not relevant to this case, we acknowledge the issues raised about this case by the commentary in Note, *Parry v. Ernst Home Center Corporation: The "Mauling" of Personal Jurisdiction Theory*, 1190 Utah L. Rev. 479 (authored by Marc Young).

in asserting jurisdiction. *Mallory Eng'g, Inc. v. Ted R. Brown & Assoc.*, 618 P.2d 1004, 1008 (Utah 1980); *see also Asahi Metal Indus. Co. v. Superior Court*, 480 U.S. 102, 113 (1987).

After reviewing the record in light of the standards articulated above, we hold that Anderson has made a prima facie showing that defendants had sufficient contacts with Utah and this litigation for assertion of personal jurisdiction consistent with due process. Facts supporting this conclusion include the following: ASPRS—(1) its committee selected Salt Lake City as a program site, (2) its committee selected Woolf as a program physician, (3) it assisted in preparing the consent form which it knew would be used in Utah, (4) it (with Dow) selected Goldwyn as monitor of treatment in the program, including anticipated treatment in Utah, (5) it investigated the potential for malpractice claims, including those that might arise in Utah, and (6) it trained Woolf, knowing he would use that training in Utah; Goldwyn—(1) helped draft the consent form, (2) supervised the proper administration of the treatment program in Utah, (3) authorized Anderson's silicone injections, and (4) assumed responsibility to monitor Anderson's treatment and to follow up if there were problems.

The foregoing facts show purposeful acts with known, significant consequences in Utah. Utah's interest in protecting Anderson from injury is compelling. Balancing all of the competing interests, we hold that it is fair to require defendants to subject themselves to trial in a Utah court for the purpose of determining whether Anderson can prove jurisdiction, and hence liability (namely, that defendants caused her injury and damages).

We vacate dismissal and remand to the trial court for trial on the merits. Because the facts supporting jurisdic-

tion overlap the facts supporting liability, the trial court must allow defendants to renew their motion to dismiss for lack of jurisdiction at the close of Anderson's evidence.

WE CONCUR:

Gordon R. Hall, Chief Justice

Richard C. Howe, Associate Chief Justice

I. Daniel Stewart, Justice

Michael D. Zimmerman, Justice

APPENDIX B

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IN THE THIRD JUDICIAL
DISTRICT COURT FOR SALT LAKE COUNTY
STATE OF UTAH

CELIA ANDERSON,

Plaintiff,

vs.

BROADBENT & WOOLF, INC., a Utah corporation, ROBERT M. WOOLF, individually, DOW CORNING CORPORATION, ROBERT GOLDWYN, an individual, and THE AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS,

Defendants.

ORDER OF
DISMISSAL

Case No. C-83-7367

Judge
Leonard H. Russon

Defendants American Society of Plastic and Reconstructive Surgeons ("ASPRS") and Dr. Robert M. Goldwyn's Motions to Quash Service of Process and for Dismissal of Plaintiff's Complaint in the above-captioned matter came on regularly for hearing before the above-entitled court on September 25, 1987 in a special setting at the hour of 9:00 a.m.; Elliott J. Williams and Larry R. Laycock of Snow, Christensen & Martineau appeared on behalf of defendants ASPRS and Robert M. Goldwyn, M.D. and Dan Bertch appeared on behalf of plaintiff Celia Anderson, and the court having heard oral argument, reviewed the pleadings and memoranda filed herein, and being fully apprised in the premises hereby finds:

1. Defendant Robert M. Goldwyn, M.D., did not have contacts with the State of Utah or plaintiff sufficient to satisfy the minimum contacts requirement for assertion of *in personam* jurisdiction pursuant to the Utah Long-Arm Statute (*Utah Code Ann.* § 78-27-24 (Supp. 1987)).

2. To assert *in personam* jurisdiction over Dr. Goldwyn under the circumstances of this case would constitute a violation of constitutional due process.

3. Dr. Goldwyn's motion for dismissal and to quash service of process should be granted on all of the grounds listed in the memoranda submitted by Dr. Goldwyn.

4. Defendant ASPRS did not have contacts with the State of Utah or plaintiff sufficient to satisfy the minimum contacts requirement for assertion of *in personam* jurisdiction pursuant to the Utah Long-Arm Statute (*Utah Code Ann.* § 78-27-24 (Supp. 1987)).

5. To assert *in personam* jurisdiction over ASPRS under the circumstances of this case would constitute a violation of constitutional due process.

6. ASPRS' motion for dismissal and to quash service of process should be granted on all of the grounds cited in the memoranda submitted by ASPRS.

7. The court finds that there is no just reason for delay and entry of judgment should be expressly directed as provided in Rule 54(b), Utah Rules of Civil Procedure.

NOW, THEREFORE, BASED UPON THE FOREGOING AND GOOD CAUSE APPEARING THEREFOR, IT IS HEREBY ORDERED:

1. Defendants ASPRS and Dr. Robert M. Goldwyn's motions for dismissal and to quash service of process be and the same are hereby granted and the plaintiff's claims against said defendants are dismissed and service of process upon them is quashed for the reason the courts of the State of Utah lack personal jurisdiction over them.

2. There is no just reason for delay and entry of this Order as a final judgment is hereby expressly directed pursuant to Rule 54(b), Utah Rules of Civil Procedure.

DATED this ____ day of October, 1987.

BY THE COURT:

Leonard H. Russon
District Court Judge

APPENDIX C

IN THE
DISTRICT COURT OF THE
THIRD JUDICIAL DISTRICT IN AND FOR
LAKE COUNTY, STATE OF UTAH

* * * * *

CELIA ANDERSON	)	
	)	
Plaintiff,	)	Transcript of:
	)	
vs.	)	JUDGE'S RULING
	)	
BROADBENT and WOOLF	)	
	)	
Defendants.	)	Case C83-7367

* * * * *

The above-entitled cause of action came on regularly for hearing before the Honorable Leonard H. Russon, a Judge of the Third Judicial District Court of the State of Utah, at Salt Lake County, Utah, on Friday, September 25, 1987.

APPEARANCES

For the Plaintiff:	DANIEL F. BERTCH Attorney at Law 6558 South Stanwich Rd. Sale Lake City, Utah
For the Defendants:	LARRY LAYCOCK ELLIOTT WILLIAMS Attorneys at Law 10 Exchange Place Salt Lake City, Utah

FRIDAY, SEPTEMBER 25, 1987

PROCEEDINGS

THE COURT: In reviewing the affidavits in this case, it would appear to this Court that Dr. Robert Goldwyn has no contact at all with the State of Utah. He has never basically been here, or owns property here, or practices here, or has any real contact this state. Nor has he ever had any personal contact with the plaintiff, nor she with him, and it would appear that she didn't really know that he existed, or his identity. And that the only possible connection between Dr. Goldwyn and Utah would be his participating in the preparation of a Consent Form and his reviewing papers sent to him in regards to Celia Anderson that would indicate she is approved for the program.

And, in view of the facts, that indicates to this Court that that does not constitute the sufficient minimal contacts required, nor the conducting of business, or the cause of committing a tort within the—or damage within the State of Utah, to bring him within the long-arm statute.

And that if, in fact, this Court were to attempt to exercise jurisdiction over him, I believe that he would be violating his due process in that he simply does not have those minimal contacts with the state, nor has availed himself of the business, to conduct the business within this state. And therefore, in regard to Dr. Goldwyn, the Motion to Quash, as well to Dismiss, is granted.

I will specifically say, so we don't have to repeat ourselves completely, it is granted for the reasons that have been set forth in the Memorandum of Points and Authorities that have been filed in support of Dr. Goldwyn.

As for the ASPRS, I think the home ruling is in order. I think likewise the fact that they are part of a study and have some sort of a relationship with Dow Chemical,

and the fact that they have some members of their organization in the state, simply are insufficient contacts to meet the minimum contact requirement. The said organization, I believe, has not purposefully availed itself of the privileges of conducting business in the State of Utah. Does not conduct business. It is a non-profit organization. It has apparently a great deal of interest in this program, but its activities are not such to constitute the minimal contacts required, and that to attempt to exercise jurisdiction over that organization would be a violation of its due process rights.

I further think that in addition— And I am going to grant the Motion to Dismiss and Quash in regards to American Society of Plastic and Reconstructive Surgeons for the reasons set forth in the Memorandum filed in support of that organization.

In addition to all of that, I do think that there is a very serious social policy program involved with all of this. The study and practice of medicine is such in our society that there is great interchange that goes on between doctors and organizations of doctors, and it is all to the betterment of society that these kinds of things occur. But if by participating as they might in non-profit organizations of non-profit enterprises, if they are going to start subjecting one another to jurisdictions of every single state, we will see a chilling effect take place that will be damaging to society at large.

I think the State Legislature clearly has recognized this by statute wherein the State of Utah there is a statutory privilege that goes to inner-medical investigations and hospitals, and otherwise, because as a public policy, we want doctors and hospitals to feel free to openly investigate procedures and practices in hospitals, and to speak freely in the meetings, without allowing such freely expressed thoughts to suddenly be staring them in courts of law.

And therefore, we have statutes that protect in that regard.

I think that sets a public policy purpose that would certainly go on to extend to other types of activities similar to the activities that we have here.

The case of Celia Anderson, if she has a case, is against Dr. Woolf, against Dow Corning. The replies— The Consent Form involved, it doesn't matter who prepared it. The fact is, there are parties to that and that would be between Dr. Woolf and Mrs. Anderson, the form itself, and possibly Dow Corning. I can't speak to that at this point. And whether or not Dr. Woolf performed as he should have, or whether or not he selected her as he should have, or whether or not the product was as it should have, are among the many issues that are reserved and will be conducted at the time of trial.

The motions, therefore, of Robert Goldwyn and the American Society of Plastic and Reconstructive Surgeons are granted and the attorneys who appear for them at this hearing may prepare the appropriate Order in that regard.

MR. WILLIAMS: Your Honor, the case has been pending for four years. It may be interminable. I would hate to have Dr. Goldwyn and the Society have to wait years before this Order becomes final. I would therefore ask the Court for a finding that there is no just cause for delay and this Order ought to be final upon signature and entry.

MR. BERTCH: I concur.

THE COURT: I will certify the Order as a final Order as to Robert Goldwyn and the American Society of Plastic and Reconstructive Surgeons.

MR. WILLIAMS: Thank you, Your Honor.

(Hearing adjourned.)

* * * *

APPENDIX D

SUPREME COURT OF UTAH
332 STATE CAPITOL
SALT LAKE CITY, UTAH 84114

February 6, 1991

OFFICE OF THE CLERK

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Celia Anderson,
Plaintiff and Appellant,
v. No. 870421

Broadbent & Woolf, Inc., a Utah corporation, Robert M. Woolf, individually, Dow Corning Corporation, American Society of Plastic and Reconstructive Surgeons, and Dr. Robert Goldwin,
Defendants and Appellees.

THIS DAY, Petition for Rehearing having been heretofore considered, and the Court being sufficiently advised in the premises, it is ordered that a rehearing be, and the same is, denied.

Geoffrey J. Butler
Clerk

FILED
JUL 1 1991
OFFICE OF THE CLERK

(2)

No. 90-1736

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1990

AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS, INC. AND ROBERT M. GOLDWYN, M.D.,

Petitioners,

v.

CELIA ANDERSON,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UTAH SUPREME COURT

RESPONDENT'S BRIEF IN OPPOSITION

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IN THE

SUPREME COURT OF THE UNITED STATES

October Term, 1990

No. 90-1736

AMERICAN SOCIETY OF PLASTIC AND
RECONSTRUCTIVE SURGEONS, INC., AND
ROBERT M. GOLDWYN, M.D.,

Petitioners,

v.

CELIA ANDERSON,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI

RESPONDENT'S BRIEF IN OPPOSITION

COUNTER STATEMENT OF FACTS

Respondent does not seek to burden the court with her own detailed statement of the facts. Respondent does wish to clarify certain facts which have either been omitted or are not apparent from the petitioners' statement.

1. The Utah Supreme Court did not rule that the American Society of Plastic and Reconstructive Surgeons (hereinafter "ASPRS") and Robert M. Goldwyn, M.D. (hereinafter "Goldwyn") were subject to personal jurisdiction in Utah. The Utah court ruled only that the facts necessary to a determination of the jurisdiction issue were so intertwined with the merits of the plaintiff's claims that the jurisdictional issue should be determined at trial. *Anderson v. American Society of Plastic and Reconstructive Surgeons*, 148 Utah Adv. Rep. 3, 5 (Nov. 1990) (see Appendix to Petition).

2. The statement of facts contained in the Petition for Writ of Certiorari contains many disputed factual statements. The petitioners' fact statement does not accurately set forth the facts as required by Supreme Court Rule 14.5 because it assumes petitioners' version of the facts is correct. There is conflicting evidence in the record from which a factfinder could reasonably find the facts to be as set forth in the following paragraphs.

3. Dow Corning Corporation ("Dow Corning") tested liquid silicone for over ten years from 1965 to 1975.

4. In 1975, the FDA approved liquid silicone for the most severe cases of facial deformity. Dow Corning elected not to market silicone under those restrictions.

5. The plastic surgeon community (principal users of silicone) was upset at the lack of availability of silicone. The ASPRS, on behalf of the plastic surgeon community, approached Dow Corning to devise a plan to make liquid silicone available to selected plastic surgeons.

6. Petitioners have incorrectly argued that the silicone injection study was sponsored by Dow Corning. (Petitioners' Brief at 3.) In fact, the study was jointly sponsored by Dow Corning and the ASPRS.

7. Dow Corning and the ASPRS agreed to jointly sponsor a new study of liquid silicone. Dow Corning and the ASPRS agreed that Dow Corning would supply the silicone and the ASPRS would provide investigators and a medical monitor for the experiment. Dow Corning and the ASPRS agreed to jointly pay the expenses of the monitor, jointly exercise control over documents used in the study, and jointly agree on all documents to be used in the study. All major aspects of the study were to be handled jointly. In

effect, Dow Corning and the ASPRS were partners in conducting the study.

8. Dr. Goldwyn agreed to be the medical monitor at the request of the ASPRS (of which his is a member). Dr. Goldwyn agreed to assist in training the investigators; to approve the admission of each patient into the study; to answer inquires as to problems of investigators; to assist in preparing reports to the FDA; to review all submissions to the FDA regarding safety or efficacy of silicone; and to be the initial contact for any complications from injection of silicone.

9. Dr. Goldwyn prepared the consent form signed by Celia Anderson. Dr. Goldwyn had the duty to assure that Dr. Woolf, Celia Anderson's treating doctor, was fully trained in his obligations as an investigator. Dr. Goldwyn had a duty to assure that Dr. Woolf followed the protocol.

10. Only Dr. Goldwyn could finalize Celia Anderson's entry into the silicone study program. Only Dr. Goldwyn could authorize Celia Anderson's injection with liquid silicone. Dr. Goldwyn knew Celia Anderson lived in Utah and would be injected with liquid silicone in Utah. If injuries were to result from the injections, Dr. Goldwyn and the ASPRS knew these injuries would occur in Utah.

11. Dr. Goldwyn reviewed Celia Anderson's medical records and diagnosed severe lipodystrophy. He then specifically approved injections of liquid silicone into Celia Anderson's body in the State of Utah.

12. After Celia Anderson's adverse reactions to the silicone, Dr. Woolf consulted continually with Dr. Goldwyn on Celia Anderson's treatment. When Dr. Woolf was replaced by Dr. Leonard as treating physician, Dr. Leonard was then in contact with Dr. Goldwyn regarding treatment.

13. Petitioners have incorrectly argued that the ASPRS had no responsibility or control over the liquid silicone study. (Petitioners' Brief at 5-6). The ASPRS in fact exercised joint control over the silicone study. The ASPRS selected the monitor and the investigators, drafted the consent form and "policed" the study. The ASPRS represented themselves as a co-sponsor or joint-sponsor. The ASPRS assisted in selecting Utah as a site for experiments. The president of the ASPRS at the time, Dr. Peterson, specifically selected Salt Lake City, Utah.

14. Petitioners have incorrectly argued that Dr. Goldwyn had no contacts and transacted no business in Utah. (Petitioners' Brief at 6). Dr. Goldwyn agreed to act as the medical monitor for a national experimental study. He agreed to screen all patients proposed for the study to assure

that they met the study protocols. Dr. Goldwyn had final responsibility for accepting a patient into the study. He knew the patients would reside in other states. Dr. Goldwyn knew Utah was one of the areas where the study would be carried out and patients would be injected. Dr. Goldwyn drafted the consent form for use in the study. Dr. Woolf, a Utah doctor, was chosen to inject the silicone in Utah. The ASPRS and Dr. Goldwyn knew the consent form they had drafted would be used in Utah by a Utah doctor to explain silicone injections to Utah patients. Dr. Goldwyn knew he would be approving experimental injections of silicone in Utah when he became monitor of the experiment. Dr. Goldwyn knew the consent form he helped draft would be used in Utah. Finally, Dr. Goldwyn oversaw the training of Dr. Woolf, a Utah doctor, in how to inject the silicone.

15. Celia Anderson suffered a severe chronic inflammatory reaction to the liquid silicone. The risk of such a reaction was well know to Dow Corning and the ASPRS, but the risk was not disclosed to Celia Anderson.

16. The ineffectiveness of surgical removal was admitted by Dow Corning to the FDA. It is impossible to remove all the injected silicone, and the body continues to react to the silicone left after surgery. Of course, surgical removal may leave severely disfiguring scars or require restoration of the

removed tissue by skin grafts. This is not explained in the consent form. The consent form implies that the injected silicone can be removed by needle (aspiration). The parties agree that is impossible.

17. Celia Anderson did not in fact have severe lipodystrophy. Her condition was misdiagnosed by Dr. Woolf and Dr. Goldwyn. Celia Anderson was never a proper candidate for injection of liquid silicone. Celia Anderson was admitted to the program in violation of the protocols.

18. The ASPRS shares liability jointly with Dow Corning and Dr. Goldwyn for improperly injecting Celia Anderson with silicone. Both the ASPRS and Goldwyn knew the experiments would be done in Utah, agreed to have Celia Anderson injected in Utah, knew that if there was damage or liability from injections, it would occur in Utah. The ASPRS and Dr. Goldwyn voluntarily came to Utah with their study. They have knowingly entered the state for jurisdictional purposes.

REASONS FOR DENYING CERTIORARI

The Utah Supreme court has not ruled that the contacts of Dr. Goldwyn and the ASPRS are sufficient to support *in personam* jurisdiction in Utah. The Utah Supreme Court only ruled that the facts which determine the jurisdictional issues are the same facts which determine the merits of Celia

Anderson's claims against the ASPRS and Dr. Goldwyn. It is reasonable to require that the jurisdiction question be determined on the evidence produced at trial. The factual disputes related to jurisdiction will be determined at the same time as the factual issues on liability.

No due process rules were ignored or rejected by the Supreme Court in remanding the case to the trial court for determination of the factual issues related to *in personam* jurisdiction. For this reason, the Petition for Writ of Certiorari should be denied.

ARGUMENT

I. THE UTAH SUPREME COURT PROPERLY DETERMINED THAT THE DISTRICT COURT HAS JURISDICTION TO DETERMINE ITS JURISDICTION BY PROCEEDING TO A DECISION ON THE MERITS

Unless this court is inclined to revisit and overrule *Land v. Dollar*, 330 U.S. 731 (1947), there is no reason to grant petitioners' request for a Writ of Certiorari in this case.

In *Land v. Dollar*, *supra*, this court held that when the question of jurisdiction is intertwined with the merits of the plaintiff's claim, a trial on the merits is a proper method for determining the question of jurisdiction. The Court stated:

> We intimate no opinion on the merits of the controversy. We only hold that the district court has jurisdiction to determine its jurisdiction by proceeding to a decision on the merits.

330 U.S. at 739.

This Court had previously determined that the mode of determining the issue of jurisdiction is left to the discretion of the trial court. *Gibbs v. Buck*, 307 U.S. 66 (1939).

Following the decisions in *Land v. Dollar*, *supra*, and *Gibbs v. Buck*, *supra*, the circuit courts have consistently followed the proposition that a trial court has the discretion to determine how the question of jurisdiction should be decided. *E.g.*, *Ten Mile Industrial Park v. Western Plains Service Corp.*, 810 F.2d 1518, 1524 (10th Cir. 1987); *Schramm v. Oakes*, 352 F.2d 143, 149 (10th Cir. 1965); *Wade v. Rogala*, 270 F.2d 280, 285 (3rd Cir. 1959); *Fireman's Fund Insurance Co. v. Railway Express Agency*, 253 F.2d 780, 784 (6th Cir. 1958).

Relying on *Land v. Dollar*, *supra*, the Tenth Circuit Court of Appeals stated in *Schramm v. Oakes* that where jurisdictional facts depend upon a decision on the merits:

> In that circumstance, the trial court should determine jurisdiction by proceeding to a decision on the merits. The purpose of postponing a determination upon a jurisdictional question when it is tied to the actual merits of the case is to prevent a summary decision on the merits without the ordinary incidents of a trial including the right to a jury. (Citations omitted).

352 F.2d at 149.

The decision of the Utah Supreme Court, in this case, adopted the holdings of the federal courts as set forth in *Land v. Dollar*, *supra*; *Gibbs v. Buck*, *supra*; and *Schramm v. Oakes*, *supra*. The Utah Court stated:

> Whether defendants caused injury to Anderson [and are thus subject to personal jurisdiction in Utah] is the central question on the merits of her claims. She is entitled to have a jury answer that question if she produces sufficient evidence.

148 Utah Adv. Rep. at 4.

The Utah Supreme Court's holding is identical to this court's holding in *Land v. Dollar*, i.e., the district court may hold a trial on the merits to determine jurisdictional questions. 330 U.S. at 739. *See*, *Schramm v. Oakes*, 352 F.2d at 149. The Utah Supreme Court stated it thus:

> Balancing all of the competing interests, we hold that it is fair to require defendants to subject themselves to trial in a Utah court for the purpose of determining whether Anderson can prove jurisdiction and hence liability (namely, that defendant caused her injury and damages).
>
> We vacate dismissal and remand to the trial court for trial on the merits. Because the facts supporting jurisdiction overlap the facts supporting liability, the trial court must allow defendants to renew their motion to dismiss for lack of jurisdiction at the close of Anderson's evidence.

148 Utah Adv. Rep. at 5.

Thus, the holding of the Utah Supreme Court is squarely in line with case law of this court as set forth in *Land v. Dollar, supra*. Unless this court intends to revisit its holding in *Land v. Dollar*, there is no basis for granting certiorari in this case.

CONCLUSION

Petitioners' claim that Utah's requirement that a non-resident medical association and one of its members go to trial to determine the issue of *in personam* jurisdiction does not violate due process.

This court has historically allowed a district court to determine the issue of jurisdiction at trial when the question of jurisdiction is dependent upon a decision on the merits. Thus, the petition for certiorari should be denied.

Respectfully Submitted,

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MOTION FILED
JUL 8 1991

No. 90-1736

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS, INC. and ROBERT M. GOLDWYN, M.D.,

Petitioners,

v.

CELIA ANDERSON,

Respondent.

On Petition For A Writ Of Certiorari To The Supreme Court Of The State Of Utah

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF OF THE AMERICAN MEDICAL ASSOCIATION, AMERICAN DENTAL ASSOCIATION, AMERICAN ACADEMY OF ALLERGY AND IMMUNOLOGY, AMERICAN ACADEMY OF DERMATOLOGY, AMERICAN ACADEMY OF OPHTHALMOLOGY, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN COLLEGE OF PHYSICIANS, AMERICAN COLLEGE OF RADIOLOGY, AMERICAN SOCIETY OF ANESTHESIOLOGISTS, AMERICAN UROLOGICAL ASSOCIATION, AND SOCIETY OF NUCLEAR MEDICINE AS AMICI CURIAE IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

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No. 90-1736

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS, INC. and ROBERT M. GOLDWYN, M.D.,

Petitioners,

v.

CELIA ANDERSON,

Respondent.

On Petition For A Writ Of Certiorari To The Supreme Court Of The State Of Utah

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

Pursuant to Rule 37.2 of the Rules of this Court, the American Medical Association, American Dental Association, American Academy of Allergy and Immunology, American Academy of Dermatology, American Academy of Ophthalmology, American Academy of Orthopaedic Surgeons, American Academy of Otolaryngology-Head and Neck Surgery, American College of Obstetricians and Gynecologists, American College of Physicians, American College of Radiology, American Society of Anesthesiologists, American Urological Association, and Society of Nuclear Medicine respectfully move for an order permitting

them to file a brief *amicus curiae*. In support of their motion, *amici* state as follows:

1. *Amici* are nonprofit professional associations collectively representing several hundred thousand physicians and dentists throughout the United States. *Amici* and their members are dedicated to maintaining high quality health care through numerous means, including the promotion and implementation of effective clinical research. They are also committed to ensuring that medical and dental services, particularly specialized services, are available to all persons in need of such treatment, regardless of the individual patient's location. The organizations represented herein are as follows:

a. The American Medical Association ("AMA") is a private, nonprofit organization that was established in 1847 to promote the art and science of medicine. AMA, with over 280,000 members, is the largest physician association in the world.

b. The American Dental Association ("ADA") is a private, nonprofit organization founded in 1859. Its purpose is to encourage the improvement of the oral health of the public and to promote the art and science of dentistry. ADA has 140,000 dentist members, representing approximately 75 percent of the nation's dentists. ADA encourages clinical trials of dental therapeutics and dental materials, instruments, and equipment. It often helps design protocols for such studies. ADA also relies on the results of clinical trials in its various programs for evaluating the safety and efficacy of dental therapeutics and dental materials, instruments, and equipment.

c. The American Academy of Allergy and Immunology ("AAAI") is a private, nonprofit medical specialty society with over 4,200 members. AAAI is the leading medical

organization for allergists and immunologists in the United States.

d. The American Academy of Dermatology ("AAD") is a private, nonprofit medical specialty society with over 8,800 members. AAD is the largest medical organization of dermatologists in the world.

e. The American Academy of Ophthalmology ("AAO") is a private, nonprofit medical specialty society, composed of 16,000, or more than 95 percent, of the nation's ophthalmologists. AAO is the largest group of ophthalmologists in the United States.

f. The American Academy of Orthopaedic Surgeons ("AAOS") is a private, nonprofit medical specialty society with 15,600 members, representing over 90 percent of all eligible, Board-certified orthopaedic surgeons in the United States and Canada. AAOS is the leading medical organization for musculoskeletal specialists. Its Center for Research provides opportunities for Academy-coordinated or Academy-initiated clinical research on a national level.

g. The American Academy of Otolaryngology-Head and Neck Surgery ("AAO-HNS") is a private, nonprofit medical specialty organization with over 9,300 members. AAO-HNS is the leading medical society for physicians specializing in head and neck surgery. Its Office of Research Development helps to coordinate multicenter clinical studies in the otolaryngology field.

h. The American College of Obstetricians and Gynecologists ("ACOG") is a private, nonprofit medical specialty organization with over 30,000 members representing 90 percent of the obstetricians and gynecologists in the United States. ACOG is the leading group of physicians specializing in health care for women. ACOG is currently the reci-

pient of a federal grant to support clinical trials in gynecologic oncology. In addition, many of ACOG's members are involved in clinical trials, and the College is often asked to recommend physicians to serve as advisors to clinical studies.

i. The American College of Physicians ("ACP"), founded in 1919, is a private, nonprofit medical specialty society with over 70,000 members specializing in the field of internal medicine. ACP comprises approximately 70 percent of all physicians in the United States practicing the specialty of internal medicine. It is the largest organization of medical specialists.

j. The American College of Radiology ("ACR") is a private, nonprofit medical specialty society with over 27,000 members. ACR is the largest organization of radiologists in the nation. ACR and its members have had extensive involvement with controlled clinical investigations. In particular, ACR has several contracts with the National Cancer Institute to organize and monitor numerous clinical cancer trials.

k. The American Society of Anesthesiologists ("ASA") is a private, nonprofit medical specialty society with nearly 29,000 members. ASA is the largest group of physicians specializing in the field of anesthesiology.

l. The American Urological Association ("AUA") is a private, nonprofit medical specialty organization with over 8,300 members worldwide. AUA is the leading medical society for physicians specializing in urology and urological surgery. It is currently involved in clinical trials in Benign Prostatic Hypertrophy, and is frequently asked to recommend physicians to serve as advisors to clinical studies.

m. The Society of Nuclear Medicine ("SNM") is a private, nonprofit, medical specialty organization representing approximately 11,000 nuclear medicine physicians, scientists, radiopharmacists, and technologists engaged in clinical practice and research. SNM is the largest organization of nuclear medicine health professionals in the United States.

2. Petitioners raise a question of national significance. If permitted to stand, the Utah Supreme Court's decision to exercise jurisdiction over the American Society of Plastic and Reconstructive Surgeons and Dr. Goldwyn, based solely on their involvement in a national clinical trial, will have a chilling effect on the willingness of medical and dental organizations and their members to participate in multistate clinical investigations. This chilling effect will be pronounced because health care organizations and individual physicians and dentists participate in clinical trials to improve medical science and the public health, rather than for commercial benefit. The Utah Supreme Court's decision also will discourage physicians, dentists, and other health care providers from treating patients from foreign states. Accordingly, the decision could have serious adverse consequences for the advancement of medical science, the quality of health care, and the availability of interstate medical and dental services.

3. The brief that *amici* request permission to file agrees with petitioners that the decision below violates the Due Process Clause of the Fourteenth Amendment. However, *amici*'s brief focuses on the national implications of the Utah Supreme Court's decision, rather than on the specific facts of this case. The brief *amicus curiae* urges that the petition should be granted because (i) the

Utah Supreme Court's exercise of jurisdiction over petitioners is unreasonable in that it fails to consider the important effect that its decision will have on the "shared interest of the several States in furthering fundamental substantive social policies," as required by this Court's decisions in *Asahi Metal Industry Co. v. Super. Court of Calif.*, 480 U.S. 102, 113 (1987), and *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980), and (ii) the Utah Supreme Court's ruling conflicts with the majority of lower federal and state court decisions regarding the exercise of personal jurisdiction under the Due Process Clause in malpractice actions against nonresident physicians, dentists, and other health care providers.

4. *Amici* sought the consent of the parties to file the accompanying brief *amicus curiae*. Petitioners consented, but respondent declined to do so. Petitioners' letter of consent is being filed contemporaneously with the Clerk of the Court. *Amici* seek leave to file their brief, in accordance with Rule 37.2. As national medical and dental associations representing thousands of physician and dentist members, *amici's* views on the questions presented will provide the Court with a broad perspective on the adverse practical ramifications for health care policy that will likely result unless the decision below is reversed, and on the need for a uniform interpretation of the Due Process Clause as it applies to the exercise of personal jurisdiction over nonresident health care providers and organizations in malpractice cases.

For the foregoing reasons, *amici* respectfully request that this Court grant their motion for leave to file the accompanying brief *amicus curiae.*

Respectfully submitted,

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No. 90-1736

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS, INC. and ROBERT M. GOLDWYN, M.D.,

Petitioners,

v.

CELIA ANDERSON,

Respondent.

On Petition For A Writ Of Certiorari To The Supreme Court Of The State Of Utah

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BRIEF OF THE AMERICAN MEDICAL ASSOCIATION, AMERICAN DENTAL ASSOCIATION, AMERICAN ACADEMY OF ALLERGY AND IMMUNOLOGY, AMERICAN ACADEMY OF DERMATOLOGY, AMERICAN ACADEMY OF OPHTHALMOLOGY, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN COLLEGE OF PHYSICIANS, AMERICAN COLLEGE OF RADIOLOGY, AMERICAN SOCIETY OF ANESTHESIOLOGISTS, AMERICAN UROLOGICAL ASSOCIATION, AND SOCIETY OF NUCLEAR MEDICINE AS AMICI CURIAE IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

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INTEREST OF THE AMICI CURIAE

Amici curiae are major national medical and dental associations and specialty societies representing hundreds of thousands of physicians and dentists. Each *amicus* and its members are committed to maintaining progress in medical science and quality health care through numerous means, including the promotion and implementation of effective clinical research. *Amici* are also dedicated to encouraging widespread availability of medical and dental services.

Amici's interest in this case is to provide the Court with certain information regarding the conduct of clinical trials and to share with the Court their understanding of the practical implications for national health care policy of the Utah Supreme Court's ruling. The Utah Supreme Court's decision to exercise jurisdiction over petitioners American Society of Plastic and Reconstructive Surgeons ("ASPRS") and Dr. Goldwyn, based solely on their involvement in a national, multistate clinical trial, is unreasonable because it will discourage medical specialty societies, physicians, dentists, and other health care providers from participating in critically important clinical investigations, thereby retarding the progress of medical and dental research.

The Utah decision will also limit patients' access to interstate health care services, particularly specialized procedures, by discouraging health care providers from treating out-of-state patients. By failing to consider or give meaningful weight to this effect, the decision below conflicts with the decisions of the majority of lower federal and state courts that have been asked to exercise personal jurisdiction over a nonresident physician, dentist, or other health care provider in a malpractice action.

Amici therefore seek to demonstrate that the public interest requires that the petition be granted so that this

Court may address the issues of national importance raised by the Utah decision and reconcile a significant conflict among the lower courts in their interpretation of the limits of the Due Process Clause.

STATEMENT

Amici adopt and incorporate herein petitioners' statement of the case. The following will provide the Court with certain essential background on the conduct of clinical trials.

1. A controlled clinical trial is a planned investigation in medicine in which one group of patients receives a test treatment and another group receives a control treatment; the two groups of patients are later compared on the basis of some pre-defined measure. Meinert, *Clinical Trials: Design, Conduct, and Analysis* 3 (1986) ("Meinert"); Kahan, Neu, Hammons, and Hillman, *The Decision to Institute Clinical Trials of Current Medical Practices* 1 (Rand 1985) ("Kahan"). Patients are usually assigned to one group or the other on a random basis. *Id.*

Controlled clinical trials have become the definitive mechanism for evaluating the therapeutic effectiveness of new drugs and medical devices. American Medical Association Council on Scientific Affairs, *Special Report, Viability of Cancer Clinical Research: Patient Accrual, Coverage, and Reimbursement*, 83 J. Nat'l Cancer Inst. 254 (1991) ("*AMA Special Report*"). They have also been widely used to evaluate the efficacy and cost-effectiveness of new and existing medical procedures. Kahan, *supra*, at 5-6.

Clinical trials are often multicentered with locations in several states and thousands of patient participants. For instance, the National Cancer Institute's Community Clinical Oncology Program covers 34 states and 62 United States communities and involves thousands of patients. Hunter,

et al., Selection Factors in Clinical Trials: Results From the Community Clinical Oncology Program Physician's Patient Log, 71 Cancer Treatment Reports 559 (1987) ("Hunter"). *See also* Office of Technology Assessment, *The Impact of Randomized Clinical Trials on Health Policy and Medical Practice* 8 (1983) ("*OTA Report*") ("Multiple Risk Factor Intervention Trial [involved] 12,866 men at 22 clinical centers to test the effect of a multifactor intervention program on mortality from coronary heart disease").

There are important reasons for conducting clinical trials in many different areas. First, multicenter studies are necessary to generate adequate patient volume. *OTA Report, supra*, at 55. Second, multistate trials allow for the enrollment of a more heterogenous group of patients, which leads to more statistically accurate results. *Id.* Third, the coordinated approach of national clinical trials avoids duplication of effort. *Id.* at 66.

Controlled clinical trials have contributed to countless major medical breakthroughs. For instance, in the cancer area, advances have been achieved in curative therapy for childhood leukemia, Hodgkin's disease, cancer of the testis, and solid tumors in children. Clinical trials have also led to a decreased mortality for premenopausal women with breast cancer. Antman, Schnipper, and Frei, *The Crisis in Clinical Cancer Research, Third-Party Insurance and Investigational Therapy*, 319 N. Eng. J. Med. 46 (1988) ("Antman"). In addition, clinical trials have been used to develop treatments for tuberculosis, AIDS, cardiovascular disease (including the artificial heart), sexually transmitted diseases, and diabetes-related blindness, to name a few.

2. The federal government plays a significant role in the funding, sponsoring, and monitoring of clinical studies. The National Institutes of Health ("NIH") is the prin-

cipal governmental sponsor of controlled clinical trials. Kahan, *supra*, at 13; Meinert, *supra*, at 40-42. According to the NIH Division of Financial Management, the agency allocated nearly $610 million to funding clinical trials in 1990. More than $525 million of this amount, or about 85 percent, was used to sponsor extramural research by private parties. Several other federal agencies also support clinical trials, including the Veterans Affairs Administration, the Department of Defense, and NASA. *OTA Report*, *supra*, at 24-26; Vaitukaitis, *The Future of Clinical Research*, 39 Clinical Research 145 (1991) ("Vaitukaitis").

The Food and Drug Administration requires clinical trials to establish the safety and efficacy of new drug therapies, 21 U.S.C. § 355 (West Supp. 1991); 21 C.F.R. § 312.21 (1990), and certain new medical devices, 21 U.S.C. §§ 360c-k (West Supp. 1991); 21 C.F.R. § 814.20 (1990). The FDA will approve a new drug application only if the safety and efficacy of the new drug are supported by "evidence consisting of adequate and well-controlled investigations, including clinical investigations" that are conducted by qualified experts. 21 U.S.C. § 355(d).

The FDA closely monitors clinical investigations of new drugs. A sponsor of a clinical investigation may not begin the study until it has submitted an investigational new drug application ("IND") and a protocol describing in detail how each phase of the study will be conducted. 21 C.F.R. §§ 312.20, 312.23(a)(6). The FDA regularly audits ongoing clinical investigations. Lisook, *FDA Audits of Clinical Studies: Policy and Procedure*, 30 J. Clin. Pharmacol. 296 (1990).

3. Clinical investigations of new drugs are typically sponsored by pharmaceutical companies. *OTA Report*, *supra* at 19. Private, nonprofit health and medical groups, such as the American Cancer Society, the American Heart

Association, the Juvenile Diabetes Foundation, and the Cystic Fibrosis Foundation also fund clinical trials of new treatments. *Id.*; Vaitukaitis, *supra*, at 145. Academic institutions occasionally sponsor controlled clinical trials, but more often they provide the facilities and personnel for government funded research and assist in recruiting patients to participate in clinical studies. In 1990, the federal government provided nearly $1 billion per year in support of such facilities and activities. *Id.*

As in this case, medical specialty societies regularly assist in the development of government and industry sponsored clinical trials. For instance, *amici* American College of Radiology, American College of Obstetricians and Gynecologists, American Academy of Orthopaedic Surgeons, American Urological Association, and American Academy of Otolaryngology-Head and Neck Surgery each participates or assists in the coordination of large-scale multicenter clinical trials in its respective field. In addition, *amicus* American Dental Association often helps design protocols for clinical trials and relies on the results of such studies in its various programs to evaluate the safety and efficacy of dental therapeutics and dental materials, instruments, and equipment.

Medical and dental societies are regularly asked to identify physicians willing to serve as monitors and investigators for clinical trials. These physicians and dentists are often the primary source of patient participants for clinical studies. *OTA Report*, *supra*, at 11. The medical monitor plays an important role in evaluating the quality of data submitted by the clinical investigators. Cox, Hynds, and Guarino, *The Management of Clinical Studies*, in *New Drug Approval Process* 191 (Guarino, ed. 1987). However, the clinical research monitor generally is not involved in the treatment of individual patients.

SUMMARY OF ARGUMENT

The Utah Supreme Court's exercise of jurisdiction over petitioners violates the reasonableness requirement of the Due Process Clause of the Fourteenth Amendment. *Asahi Metal Industry Co. v. Super. Court of Calif.*, 480 U.S. 102, 113 (1987); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980). The decision to exercise jurisdiction is unreasonable because it is inimical to the "shared interest of the several States in furthering fundamental substantive social policies," *id.*, in that it will discourage medical specialty societies, dental associations, physicians, dentists, and other health care providers from participating in controlled clinical trials. Medical and dental societies and their members participate in clinical studies to further the public health and to advance medical science. They do not participate for commercial benefit. Their incentive to participate in clinical trials will be greatly reduced if they are effectively subject to jurisdiction in every state in which some phase or aspect of a national clinical investigation is conducted. As a result, the progress of important medical research will be impeded.

This case is of national significance because of the key role that clinical trials play in the advancement of medical science and quality health care. In addition, the federal government, as one of the primary sponsors of clinical trials, has a significant national investment in this scientific process. The Utah Supreme Court's failure to consider these national interests directly conflicts with the due process analysis required by this Court's decisions in *Asahi* and *World-Wide Volkswagen*.

The Utah Supreme Court also failed to consider the more generalized effect that its decision will have on the willingness of health care providers to treat out-of-state patients. By exposing a nonresident physician to long-arm

jurisdiction when he has not treated the patient, in Utah or anywhere else, and has no other significant contacts with Utah, the decision will likely limit the availability of out-of-state health care services, particularly highly specialized services. The Utah Supreme Court's failure to consider and give meaningful weight to these interstate implications conflicts with the decisions of the majority of lower federal and state courts that have been asked to exercise jurisdiction over nonresident physicians, dentists, and other health care providers in malpractice actions.

ARGUMENT

I. THE UTAH SUPREME COURT'S EXERCISE OF JURISDICTION OVER PETITIONERS IS UNREASONABLE BECAUSE THE COURT FAILED TO CONSIDER THE ADVERSE EFFECTS THAT THE DECISION WILL HAVE ON THE PROGRESS OF MEDICAL RESEARCH AND QUALITY OF HEALTH CARE.

The Utah Supreme Court's decision is unreasonable because the court utterly failed to consider the chilling effect that its ruling will have on the willingness of medical and dental societies, individual physicians and dentists, and other health care providers to participate in controlled clinical trials. This result is of national significance because it will impede the progress of medical research and the advancement of quality health care.

This Court has established a two-part test for asserting specific jurisdiction over the person under the Due Process Clause of the Fourteenth Amendment. First, due process is satisfied only where the defendant has "purposefully established 'minimum contacts' in the forum state" that give rise to the cause of action. *Burger King v. Rudzewicz*, 471 U.S. 462, 474 (1985) (quoting *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). Second, if

it has been decided that a defendant purposefully established the requisite minimum contacts, a court must determine whether the exercise of personal jurisdiction would offend " 'traditional notions of fair play and substantial justice.' " *Asahi Metal Industry Co. v. Super. Court of Calif.*, 480 U.S. 102, 113 (1987) (quoting *International Shoe*, 326 U.S. at 316). In other words, the court must decide whether it would be reasonable to exercise jurisdiction over the defendant. *Id.* at 113-15 (unreasonable to exercise jurisdiction over Japanese manufacturer of tire valve stems in part because of foreign policy implications). This is not an optional inquiry; the court must address both parts of the due process test before it may exercise long-arm jurisdiction. *Id.*

The determination of reasonableness turns on the analysis of several factors, including "the interests of the forum State" and " 'the shared interest of the several States in furthering fundamental substantive social policies.' " *Asahi*, 480 U.S. at 113 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980)). Here again, the court *must* weigh all of the reasonableness factors in its decision. *Id.* at 115 ("*World-Wide Volkswagen* also admonished courts to take into consideration the interests of the 'several States'. . . in the advancement of substantive policies"). Even if the forum state has a strong interest in exercising jurisdiction over a nonresident defendant, "the Due Process Clause, acting as an instrument of interstate federalism, may sometimes act to divest the State of its power to render a valid judgment." *World-Wide Volkswagen*, 444 U.S. at 294.

Amici agree with and adopt petitioners' position that their activities in Utah are too attenuated to satisfy the minimum contacts part of the due process test. *Amici*'s purpose here is to show that the exercise of jurisdiction over petitioners is unreasonable because the Utah court

failed to consider the adverse effect that its ruling will have on our national interest in the advancement of medical progress and public health through clinical research.

That there is a strong national interest in the conduct of controlled clinical trials can hardly be disputed. " '[N]o other method for studying the merits of clinical treatment regimens can approach the precision of estimating the effects and the strength of inference permitted by sound [randomized controlled trials].' " Kahan, *supra*, at 6 (citations omitted).[1]

The fact that the federal government is a principal sponsor of clinical trials is further evidence of a strong national interest and investment in this process. Moreover, our nation's system of new drug approval is dependent upon the performance of clinical trials. Clinical trials are also an essential tool in evaluating the cost-effectiveness of alternative therapies.

The Utah Supreme Court's decision comes at a time when clinical research in many fields is already in a state of near crisis. For instance, clinical cancer trials are hindered by the increasing cost of providing care, federal funding constraints, and the reluctance of third party payors to reimburse for investigational treatments. Antman, *supra*, at 46; Durant, *Current Status of Clinical Trials*, 65 Cancer 2371, 2372-73 (1990). The AMA's Council on Scientific Affairs has observed that "This environment has the potential to seriously compromise clinical research

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[1] In the cancer field, for example,

> The ability to administer experimental therapy is fundamental to medical progress. If new treatments cannot be tested, the state of the art will freeze at its current level. To the extent that these newly discovered treatments remain inaccessible to the average cancer patient, lives will be lost unnecessarily.

Wittes, *From Research to Approved Treatment: Overcoming the Obstacles*, 25 Seminars in Hematology 38, 42 (1988).

just at the time when great strides in such fields as molecular biology, genetics, and medical physics argue persuasively for a significant augmentation of the research effort." *AMA Special Report, supra,* at 254.

In addition to these obstacles, the viability of clinical trials is threatened by insufficient patient accrual or recruitment. Many clinical studies are being delayed or aborted because of an inability to obtain subject populations of sufficient size or heterogeneity.[2] Wittes and Friedman, *Accrual to Clinical Trials,* 80 J. Nat'l Cancer Inst. 884 (1988); LaRue, *et al., Acute Stroke Therapy Trials: Problems in Patient Accrual,* 19 Stroke 950 (1988).

As in this case, sponsors of clinical trials regularly turn to medical societies for assistance in identifying physicians willing to participate as medical monitors and clinical investigators. These physicians are often the most important source of patient recruitment in clinical trials. *OTA Report, supra,* at 11; *AMA Special Report, supra,* at 254-55. Recognizing this fact, the National Cancer Institute has launched a drive to increase physician involvement in clinical trials in hopes of doubling patient accrual rates. *AMA Special Report, supra,* at 256.

The Utah Supreme Court's ruling will discourage medical specialty societies and other health care organizations from assisting sponsors in developing clinical trials and in identify-

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[2] As the AMA's Council on Scientific Affairs has stated,

> In the design of [clinical] trials, the establishment of appropriate sample size is necessary to ensure acceptable levels of risk for error when a hypothesis is tested. Thus, it is critical that the predetermined sample size be attained by entering eligible patients in cancer clinical trials in sufficient numbers and in a timely fashion. Presently, clinical research in cancer is being threatened by inadequacies in the accrual of patients for clinical trials.

AMA Special Report, supra, at 254.

ing physicians and dentists willing to participate in such studies, either as medical monitors or as clinical investigators. It also will deter physicians and dentists from agreeing to participate in clinical studies, particularly as clinical monitors. The decision will have a similar impact on academic institutions, non-profit health organizations, non-physician researchers, and any other individual or organization that participates in clinical research activities.

This chilling effect will likely be pronounced because medical and dental societies and individual health care providers participate in clinical trials for reasons other than commercial benefit. Although they may receive some nominal reimbursement for their time and efforts, their primary purpose in participating in clinical trials is to contribute to the advancement of medical science and the improvement of the quality of health care.[3] If the decision below were widely followed by other courts, medical and dental associations and clinical monitors essentially could be subject to jurisdiction in every state in which some phase or aspect of a clinical trial was conducted. In light of the minimal reimbursement that they typically receive for their involvement in clinical research, the threat of being haled into court in a jurisdiction hundreds or thousands of miles away to defend costly, time consuming litigation will almost certainly deter participation in clinical studies

[3] This lack of commercial motive, in and of itself, makes the exercise of jurisdiction particularly inappropriate in this case. *See Kulko v. Super. Court of Calif.*, 436 U.S. 84, 97 (1978) (exercise of jurisdiction violates due process in part because appellant did not seek "a commercial benefit from solicitation of business from a resident of California that could reasonably render him liable to suit in state court"); *State ex rel. Wichita Falls General Hosp. v. Adolf*, 728 S.W.2d 604, 610 (Mo. App.), *cert. denied*, 484 U.S. 927 (1987) (refusing to exercise jurisdiction over nonresident hospital in part because hospital participated in organ donation program for "moral and humanitarian reasons").

by the ablest and most responsible health care organizations and individual health care providers.[4]

The ultimate result will be to stymie the progress of important medical research by making it extremely difficult to attract the key personnel needed to conduct a clinical study. The decision also will directly countermand efforts by the federal government and others to increase patient accrual in national clinical trials in that it will discourage participation by the people best situated to enroll clinically appropriate patients.

Even if the decision below does not completely deter medical societies and physicians from participating in clinical trials, it will at least discourage them from participating in large, multicentered clinical trials involving patients in many states. These large-scale national trials are crucial to the progress of medical research.[5]

Petitioners' limited contacts with Utah must be viewed in light of these adverse consequences for national health

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[4] *See* Kahan, *supra*, at 45 ("if clinical trials of treatments become the target of further litigation, there could be an unwillingness by physicians to participate in such investigations, to the detriment of medicine and society in general") (citing Norman, *Clinical Trial Stirs Legal Battles*, 227 Science 1316 (1985)).

[5] Given the sweeping nature of the Utah Supreme Court's exercise of jurisdiction, its decision may also discourage medical societies from issuing national practice parameters for fear of being subject to jurisdiction in malpractice actions filed in distant forums. Practice parameters are strategies for patient management developed to assist physicians in clinical decision-making. Such parameters play an important role in maintaining and standardizing the quality of patient care and in controlling the overall cost of medical services. Kelly and Swartwout, *Development of Practice Parameters by Physician Organizations*, 16 Quality Rev. Bull. 54 (1990). Many of the *amici* medical specialty organizations issue practice parameters and are concerned about the precedential effect that the Utah Supreme Court's decision will have in malpractice actions in which the use of practice parameters is a liability issue.

care policy. It is particularly unreasonable to exercise jurisdiction where to do so is likely to have such a detrimental effect on clinical research efforts and where petitioners have received no commercial benefit from their attenuated forum contacts. The Utah Supreme Court failed to consider this important aspect of the due process analysis.[6]

II. THE UTAH SUPREME COURT'S FAILURE TO CONSIDER THE EFFECT OF ITS DECISION ON THE AVAILABILITY OF HEALTH CARE SERVICES CONFLICTS WITH THE DECISIONS OF THE MAJORITY OF LOWER COURTS THAT HAVE INTERPRETED THE DUE PROCESS CLAUSE IN MALPRACTICE ACTIONS AGAINST NONRESIDENT HEALTH CARE PROVIDERS.

The practical implications of the Utah Supreme Court's decision for national health care policy extend well beyond its likely effect on the progress of multistate clinical research. If allowed to stand, the decision below is also likely to limit the availability of interstate health care services. By ignoring this additional effect, the ruling below conflicts with the decisions of the majority of lower courts that have been asked to exercise personal jurisdiction over nonresident health care providers in malpractice cases.

Dr. Goldwyn did not diagnose or treat respondent in Utah or anywhere else. The exercise of jurisdiction over Dr. Goldwyn was based solely on his out-of-state activities as medical monitor. He had no other contacts with Utah. Nevertheless, the Utah Supreme Court exercised jurisdic-

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[6] *Amici* do not mean to suggest that respondent is not entitled to any remedy for her injuries. The argument here is not that petitioners are immune from suit, only that it was unreasonable for the Utah Supreme Court to exercise personal jurisdiction over them in light of their limited contacts with Utah and the national interest in maintaining the progress of clinical trials.

tion over him because he engaged in "purposeful acts with known, significant consequences in Utah." Petition at 8a. But this reasoning would apply with even greater force if respondent had traveled to Massachusetts, and Dr. Goldwyn had actually treated her there. In short, the Utah Supreme Court's decision is so overreaching that it arguably encompasses any case in which a nonresident physician treats a Utah patient in a foreign state, and the patient suffers an adverse reaction after returning to Utah.

In view of its sweeping rationale, the Utah Supreme Court's decision will not only have a specific deterrent effect on participation in clinical trials, it will also have a more generalized chilling effect on the willingness of nonresident physicians and health care providers to treat Utah patients outside of Utah. If this Court allows the Utah Supreme Court's ruling to stand, other state and federal courts will be more likely to follow it. The ultimate effect will be to balkanize our interstate system of health care. Citizens of one state will find that state boundaries constitute an impenetrable barrier to securing the best, and sometimes the *only*, available health care services—*e.g.*, heart and liver transplants, cancer therapy, kidney dialysis, and other sophisticated treatments.[7] In metropolitan areas that cut across state lines, the result would be to encourage the duplication of highly sophisticated facilities. Such results conflict with the "shared interest of

[7] By discouraging participation in multistate clinical trials, the Utah Supreme Court's decision also will have the more immediate effect of limiting the availability of state-of-the art therapies offered by clinical trials. Hunter, *supra*, at 559. In many cases, a patient's only hope for recovery is by undergoing an experimental treatment. *Report of the Presidential Commission on Human Immunodeficiency Virus Epidemic* 54 (1988) (advocating greater access to drug trials to provide the hope and possibility of treatment for thousands of HIV patients).

the several States," *World-Wide Volkswagen*, 444 U.S. at 292, in ensuring that specialized health care services are available to all citizens, regardless of which state they live in, at the lowest possible cost.

By failing to consider or give credence to the effect of its decision on access to interstate health care services, the Utah Supreme Court not only disregarded the decisions of this Court, *Asahi*, 480 U.S. at 113; *World-Wide Volkswagen*, 444 U.S. at 292, it also has positioned itself in direct conflict with the preponderance of courts that have addressed the personal jurisdiction issue in malpractice actions against nonresident physicians and other health care providers.

There is now a long line of cases, starting with the Ninth Circuit's decision in *Wright v. Yackley*, 459 F.2d 287 (9th Cir. 1972), in which courts interpreting the Due Process Clause have *refused* to exercise jurisdiction over nonresident physicians or health care providers, either in whole or in part, because to do so could have the effect of restricting the availability of interstate health care services. In almost all of these cases, the defendant health care provider had greater contact with the forum state than Dr. Goldwyn had with Utah in this matter.

In *Wright*, the Ninth Circuit held that it would violate the Due Process Clause to exercise jurisdiction in Idaho over a South Dakota physician. The physician had initially treated a patient in South Dakota. After the patient moved to Idaho, the physician mailed copies of the patient's prescription to an Idaho pharmacist. The court held that in cases of personal services, the focus should be on the places where the services are rendered. It stated that:

> In our opinion, a state's dominant interest on behalf of its citizens in such a case as this is not that they should be free from injury by out-of-state doctors, but

> rather that they should be able to secure adequate medical services to meet their needs wherever they may go. 459 F.2d at 291.

The court concluded that it would be unreasonable to exercise jurisdiction over the nonresident physician.

Likewise, in *Gelineau v. New York Univ. Hosp.*, 375 F. Supp. 661, 667-68 (D.N.J. 1974), the court, relying on the reasoning in *Wright*, found that due process would not permit the exercise of jurisdiction in New Jersey over a New York hospital and its blood suppliers in a case in which a New Jersey patient was allegedly given an infected blood transfusion in the New York hospital. The court stated that the exercise of jurisdiction

> . . . would have a chilling effect on the availability of professional services to non-residents. Professionals in the medical field, for example, concerned with one of the most rapidly advancing sciences of modern times, would be hesitant to treat a non-resident if they knew that thereafter, upon the receipt of a registered letter, they could be compelled to travel to a foreign state, and there to account, under the laws of that state, for the services which were sought from them and rendered by them at home. *Id.*

In *Simmons v. State*, 206 Mont. 264, 670 P.2d 1372 (1983), the Montana Supreme Court followed *Wright* and *Gelineau* in finding that it was unreasonable to exercise jurisdiction over the Health Division of the Oregon Department of Human Resources for alleged negligent testing of metabolic disorders in a newborn child. The Oregon agency provided this testing service to several nearby states that lacked the capability to perform it themselves.

The *Simmons* court stated that "[t]he reasonableness of asserting jurisdiction over Oregon must also be assessed in light of the shared interest of both Montana and Oregon in advancing the state of quality medical testing technology." 670 P.2d at 1383. It concluded that:

> If we found that jurisdiction was reasonable under the given facts, we would be creating precedent for jurisdiction over Oregon by other states that contracted with it for regional blood testing services. In that event, we think it highly likely that Oregon might refrain from providing the service rather than risk defending its interests in the several foreign states. Thus, we find that proper respect for the mutual interests of interstate access to medical services and quality rendering of those same services requires that plaintiff pursue his malpractice claim in the Oregon courts. *Id.* at 1384.

In *State ex rel. Wichita Falls General Hosp. v. Adolf*, 728 S.W.2d 604, 610 (Mo. App.), *cert. denied*, 484 U.S. 927 (1987), the Missouri Court of Appeals cited similar reasons for refusing to exercise jurisdiction over a Texas hospital that provided the wrong type of organ donor heart to a patient in Missouri:

> If the threat of having to defend a potential malpractice action, meritorious or otherwise, in a far distant jurisdiction serves to cause even one hospital to refuse to provide an organ necessary to keep a Missouri resident alive the results far outweigh the inconvenience of requiring Missouri residents to sue in the hospital's home forum. *Id.*

The majority of published decisions in malpractice cases against nonresident physicians and other health care providers have agreed with the balance of interests analysis used in *Wright*, *Gelineau*, *Simmons*, and *Wichita Falls* and thereby dismissed such actions for lack of personal jurisdiction.[8] This is precisely the approach that is re-

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[8] *See, e.g., Rann v. McInnis*, 789 F.2d 374, 376 (6th Cir. 1986); *Wolf v. Richmond County Hosp. Auth.*, 745 F.2d 904, 911 (4th Cir. 1984), *cert. denied*, 474 U.S. 826 (1985); *Lemke v. St. Margaret Hosp.*, 552 F. Supp. 833, 837 (N.D. Ill. 1982) (subsequent history

(Footnote continued on following page)

quired by this Court's decisions in *Asahi* and *World-Wide Volkswagen.*

The Utah Supreme Court's decision is not just an isolated aberration. At least two other courts have exercised jurisdiction over nonresident health care providers in malpractice actions, in spite of the possible adverse effects on the availability of interstate health care services. For instance, in *McGee v. Riehkof*, 442 F. Supp. 1276 (D. Mont. 1978), the Montana district court exercised jurisdiction over an out-of-state ophthalmologist who had treated a Montana patient in Utah and then gave an allegedly negligent telephone diagnosis to the patient after the patient had returned to Montana. The court recognized the need to preserve access to interstate medical services, but ruled that this need was outweighed by Montana's interest in deterring malpractice by nonresident physicians. This conclusion not only conflicts with *Wright* and its progeny, it is in direct opposition to the Montana Supreme Court's subsequent decision in *Simmons*. Likewise, just last year, the United States Court of Appeals for the Tenth Circuit held that the forum state's interest in deterring medical malpractice against its residents outweighs the "incremental deterrent effect on doctors who provide health care to citizens of foreign states." *Kennedy v. Freeman*, 919 F.2d 126 (10th Cir. 1990) (exercising jurisdiction over Texas physician who allegedly made a misdiagnosis of a cancerous skin lesion that was sent to him by an Oklahoma physician on behalf of an Oklahoma patient).

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[8] *continued*
omitted); *Hume v. Durwood Medical Clinic, Inc.*, 318 S.E.2d 119, 123 (S.C. App. 1984), *cert. denied*, 474 U.S. 848 (1985); *Woodward v. Keenan*, 79 Mich. App. 543, 261 N.W.2d 80, 83 (1978) (subsequent history omitted).

Thus, the Utah Supreme Court's decision adds to a significant conflict among the lower courts regarding the importance of the availability of interstate health care services where courts are asked to exercise personal jurisdiction over nonresident health care providers. As a result, whether a physician, dentist or other health care provider is subject to long-arm jurisdiction for allegedly mistreating an out-of-state patient now depends to a large extent on the fortuity of the patient's state of domicile. In some states, *e.g.*, Montana, the jurisdictional decision may turn on whether the provider is sued in federal or state court.

This is hardly the type of predictability that the Due Process Clause is supposed to provide nonresident defendants. *World-Wide Volkswagen*, 444 U.S. at 297. Health care providers are entitled to know the type of conduct and connection with a forum state that make it reasonable for them to "anticipate being haled into court there." *Id.*

This Court should grant the petition and review this case to resolve the conflict in the courts below by providing a uniform interpretation of the jurisdictional requirements of the Due Process Clause in malpractice actions involving nonresident health care providers and organizations.

CONCLUSION

For the foregoing reasons, *amici* respectfully request that the petition for a writ of certiorari be granted.

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IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1990

AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS, INC. AND ROBERT M. GOLDWYN, M.D.,

Petitioners,

v.

CELIA ANDERSON,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UTAH SUPREME COURT

RESPONDENT'S SUPPLEMENTAL BRIEF IN RESPONSE TO BRIEF OF AMICI CURIAE

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STATEMENT OF FACTS

Respondent does not wish to burden the court by restating the facts in this case. Respondent's version of the critical facts is set forth in her Brief in Opposition to Petition for Writ of Certiorari at 1-6 (hereinafter "opposition brief"). The Utah Supreme Court recognized that the cricial factual issues upon which a determination of the jurisdictional issues depend, are in dispute. *See, Anderson v. American Society of Plastic and Reconstructive Surgeons*, 807 P.2d 825 (Utah 1990).

REASONS FOR DENYING CERTIORARI

The Utah Supreme court has not ruled that the contacts of Dr. Goldwyn and the ASPRS are sufficient to support *in personam* jurisdiction in Utah. The Utah Supreme Court only ruled that the facts which determine the jurisdictional issues are the same facts which determine the merits of Celia Anderson's claims against the ASPRS and Dr. Goldwyn. Therefore, the factual disputes related to jurisdiction will be determined at the same time as the factual issues on liability. Because the opinion of the Utah Supreme Court in *Anderson, supra*, does not finally determine the jurisdiction issue, but merely remands the case for a determination of the factual issues at trial, there is no reason to grant certiorari at this time.

ARGUMENT

I. THE UTAH SUPREME COURT PROPERLY DETERMINED THAT THE DISTRICT COURT HAS JURISDICTION TO DETERMINE ITS JURISDICTION BY PROCEEDING TO A DECISION ON THE MERITS

This Court's decision in *Land v. Dollar*, 330 U.S. 731 (1947) controls this case. *Land v. Dollar* holds that when the question of jurisdiction is interwined with the merits of the plaintiff's claim, a trial on the merits is a proper method for determining the question of jurisdiction. In *Land*, this Court stated:

> We intimate no opinion on the merits of the controversy. We only hold that the district court has jurisdiction to determine its jurisdiction by proceeding to a decision on the merits.

330 U.S. at 739.

Certiorari should be denied unless this Court wishes to revisit *Land v. Dollar* and overrule its holding.

II. THE LEGAL ISSUES RAISED BY AMICI CURIAE ARE NOT PROPERLY BEFORE THE COURT

Amici has argued to this Court that:

> *Amici's* interest in this case is to provide the Court with certain information regarding the conduct of clinical trials and to share with the Court their understanding of the practical implications for national health care policy of the Utah Supreme Court's ruling. The Utah Supreme Court's decision to exercise jurisdiction over petitioners American

> Society of Plastic and Reconstructive Surgeons ("ASPRS") and Dr. Goldwyn, based solely on their involvement in a national, multistate clinical trial, is unreasonable because it will discourage medical specialty societies, physicians, dentists, and other health care providers from participating in critically important clinical investigations, thereby retarding the progress of medical and dental research.
>
> The Utah decision will also limit patients' access to interstate health care services, particularly specialized procedures, by discouraging health care providers from treating out-of-state patients. By failing to consider or give meaningful weight to this effect, the decision below conflicts with the decisions of the majority of lower federal and state courts that have been asked to exercise personal jurisdiction over a nonresident physician, dentist, or other health care provider in a malpractice action.
>
> *Amici* therefore seek to demonstrate that the public interest requires that the petition be granted so that this Court may address the issues of national importance raised by the Utah decision and reconcile a significant conflict among the lower courts in their interpretation of the limits of the Due Process Clause.

Brief of *Amici Curiae* at 1-2 (hereinafter "*Amici* Brief").

The problem with the *amici* argument is that the issue briefed by *amici* is not before this court. The whole of the *amici* argument presupposes that the Utah Supreme Court has held that Goldwyn and the ASPRS are in fact subject to jurisdiction of the Utah courts "based solely on their

involvement in a national, multistate clinical trial." *See*, *Amici* Brief, *supra* at 1.

However, the Utah Supreme Court merely ruled that personal jurisdiction depends upon facts which were in dispute and which must be determined at trial. *See*, opposition brief, *supra* at 9-10. Whether Goldwyn and the ASPRS caused damage to Celia Anderson in Utah is a hotly contested fact issue. A jury will decide whose version of the facts is correct. The nature and extent of Goldwyn's and the ASPRS's activities in Utah will also be decided by a jury.

Once the jury has determined these factual issues, the trial court can then apply due process principles and determine if personal jurisdiction is proper in this case. As stated by the Utah court, the facts which determine jurisdiction are also the facts which determine liability. *Anderson*, 807 P.2d at 825.

The Utah Supreme Court did not determine the ultimate jurisdictional question. It remanded the case for trial on the jurisdictional question. *Id.* The only issue subject to review is whether it was proper to remand the case for determination of the jurisdictional issue at trial.

CONCLUSION

The decision of the Utah Supreme Court that the jurisdiction question must be determined at trial is squarely in line

with this Court's holding in *Land v. Dollar*, *supra*. This Court has historically allowed the question of jurisdiction to be determined at trial when the same factual issues determine both liability and jurisdiction. Therefore, unless this Court intends to revisit and overrule *Land v. Dollar*, *supra*, the Petition for Writ of Certiorari should be denied.

Respectfully Submitted,

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